

Transparency in Federal Policy-Making: the Case of Biotechnology in Animals Intended
for Human Consumption

by
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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

This research project examines the degree of transparency of the Canadian Federal Government's decision-making processes and institutions with respect to the human consumption of animals produced through modern biotechnology (biotechnology-produced animals). It provides a timely study of the Federal Government's decision-making process; as of January 2013 the government has yet to determine whether, and how, biotechnology-produced animals are to be approved for human consumption. Foods that contain genetically modified organisms (GMOs) are already commercially widely available in Canada. Research is well underway to see if biotechnology-produced animals may also be developed and introduced into the food system.

Government decisions regarding the human consumption of biotechnology-produced animals have the potential to revolutionize food systems globally and nationally. This thesis offers an analysis of primary and secondary data focusing on the degree of federal transparency with respect to regulating GMO foods generally and, more specifically, the emerging policy issues around biotechnology-produced animals. This exploration sets the stage for the following investigation of barriers as well as opportunities to fostering federal transparency with respect to policy and regulatory decisions regarding GMO foods. Findings are directed towards members of the communities of interest who are interested in questions relating to the degree of federal transparency and government approaches to foods that contain material produced through modern biotechnology.

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List of Abbreviations

Biotechnology-produced animals	Animals produced through modern biotechnology
Biotech foods	Foods produced through modern biotechnology
CBI	Confidential Business Information
CCGD	Canadian Council of Grocery Distributers
CEPA	Canadian Environmental Protection Act
CFIA	Canadian Food Inspection Agency
CIELAP	Canadian Institute for Environmental Law and Policy
DFO	Department of Fisheries and Oceans
DNA	Deoxyribonucleic acid
EAR	Environmental Assessment Regulations
EII	Environmental Impact Initiative
FDA	Food and Drugs Act
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organism
HECSB	Healthy Environments and Consumer Safety Branch
HPFB	Health Products and Food Branch of Health Canada
MOU	Memorandum of Understanding
OAG	Office of the Auditor General of Canada
RSC	Royal Society of Canada
NSNR	New Substance Notification Regulations
NSNR (Organisms)	New Substance Notification Regulations (Organisms)
PNT	Plants with Novel Traits
rDNA	recombinant deoxyribonucleic acid

* Foreword: For this thesis, genetically engineered (GE), genetically modified (GM) and biotechnology-produced are used interchangeably to refer to organisms that have been produced through genetic changes at the gene level unless noted otherwise (i.e. in a Private Member's Bill). The researcher has tried to use biotechnology-produced as often as possible.

Chapter 1: Foods Derived through Modern Biotechnology, Transparency and the Canadian Federal Government: Introduction

1.1 Context

Food Democracy is an issue of growing concern globally and domestically in Canada (Food Secure Canada, 2011; Hassanein, 2003; Johnson, Biro & MacKendrick, 2009; Lang, 1999; Navdanya, 2009; Small Planet Institute, 2012; UN News Center, 2008). Yet surprisingly in Canada the general public knows very little about how genetically engineered (GE) foods are managed, produced and regulated. For example, the last major inquiry commissioned by the Canadian Federal Government was in 2001 by the Royal Society of Canada. As discussed below, the recommendations in this inquiry were largely ignored. This thesis explores the degree of transparency that exists with respect to Federal Government policies, decision-making processes, institutions, and regulations surrounding foods produced through modern biotechnology. It does so in the context of food democracy. As stated by a former NDP MP “There is no better area to study in terms of lack of government transparency and accountability than these foods” (NDP-J).

1.1.1. The Key Issues

Many issues with respect to regulations concerning the human consumption of animals produced through modern biotechnology (i.e. biotechnology-produced animals) are confidential or have not been considered in the Canadian Government’s current policy approaches. These issues include, but are not limited to:

- The confidential nature of the regulatory processes.
- The question of how and whether economic, ethical, and social risks or impacts will be considered by the Federal Government.
- The lack of public knowledge about whether policies for foods produced through modern biotechnology will be considered.
- If it will be mandatory to label food products that contain biotechnology-produced animals.
- How regulators will assess the scientific data submitted by an applicant.
- How regulators will decide what scientific data needs to be submitted by applicants.

- Whether the public will be notified if an application is being, or has been, submitted.

As the following discussion elaborates, Government transparency is needed when dealing with these issues: all of which have serious ethical, socio-ecological and governance implications. First, however, some background information provides context for the discussion.

The *Canadian Environmental Protection Act* (1999) defines biotechnology as "the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms, in their natural or modified forms." In Canada the term "animal biotechnology" is considered to be an extension of the definition of biotechnology. As directly stated on the Canadian Food Inspection Agency's website the term may include, but is not limited to, the following categories of animals,

1. *Genetically engineered or modified animals in which genetic material has been added, deleted, silenced or altered to influence expression of genes and traits.*
2. *Clones of animals derived by nuclear transfer from embryonic and somatic cells.*
3. *Chimeric animals that have received transplanted cells from another animal.*
4. *Interspecies hybrids produced by any methods employing biotechnology.*
5. *Animals derived by in vitro cultivation such as maturation or manipulation of embryos.* (Canadian Food Inspection Agency, 2012a)

The definition includes animals that have been produced through genetic changes at the organism level (through traditional biotechnology techniques such as selective breeding and hybridization), as well as animals that have been produced through genetic changes at the gene level (through modern biotechnology techniques such as recombinant DNA techniques (genetic engineering) (Government of Canada, 2008b). This research paper focuses on animals derived through modern biotechnology.

In order to manufacture, import or sell an animal derived from modern biotechnology (a biotechnology-produced animal) in Canada, the producer or manufacturer must notify Environment Canada "so that the animal undergoes a safety assessment for potential impacts to the environment" (Canadian Food Inspection Agency, 2012a). The assessments are co-administered by Environment Canada and Health Canada under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) and the *New Substance Notification Regulations (Organisms)* NSNR (Organisms). The environmental aspects of the notification are evaluated by Environment Canada and the human health aspects are evaluated by Health Canada (CFIA,

2012a). Manufacturers or importers of new substances in products regulated by the *Food and Drugs Act*, including food products derived from biotechnology-produced animals, are also required to submit notification under the *NSNR (Organisms)* so that an environmental assessment may be conducted (Health Canada, 2010b).

As of December 2012, no food products derived from biotechnology-produced animals had been approved for release into the food chain in Canada. These food products are classified as “novel foods” under Division 28, Part B, of the *Food and Drug Regulations*.¹ Health Canada is the primary department in charge of approving the release of novel foods into the food supply chain.

Novel foods are subject to a pre-market safety notification conducted by Health Canada to assess the food’s human health safety and nutritional adequacy. The criteria for Health Canada’s scientific evaluation are described in Health Canada’s *Guidelines for the Safety Assessment of Novel Foods* (Volumes I and II). Guidelines “provide transparency in decision-making and fill in details sometimes missing from the strict nature of legal language in laws or regulations” (Health Canada, 2010d). As of December 2012, the *Guidelines for the Safety Assessment of Novel Foods* (Volumes I and II) were last updated in 2006. The guidelines state that the section for Novel Foods Derived from Animals is “Under Development” (Health Canada. Food Directorate Health Products and Food Branch, 2006). According to Health Canada’s website “safety assessment criteria for novel foods derived from animals are under development” (Health Canada. Food Directorate. Health Products and Food Branch, 2006, p. 5).

Health Canada uses the concept of substantial equivalence as a guide in the safety assessment of novel foods (Health Canada, 2006d). The food product is compared to its conventional counterpart already found in the food supply which has a history of safe use. The focus is placed on similarities and differences in composition, including nutritional value and toxicity. Substantial equivalency is determined through comparing the novel food to its conventional counterpart’s set of molecular, compositional and nutritional data, if one exists (Andree, 2002; Health Canada, 2006d). It is unknown how the concept of substantial equivalence will be applied to assess the safety and nutritional adequacy of a food product that contains biotechnology-produced animals before it can be sold in Canada.

¹ The Food and Drug Regulations can be found on the Department of Justice Canada website

February 2010, the genetically engineered (GE) Enviropig™, a biotechnology-produced animal, was approved for reproduction and exportation for the first time in Canada. The Enviropig™ was created at the University of Guelph in 1999 with the intent to reduce levels of phosphorous found in pig excrement (University of Guelph, 2010). The University had submitted paperwork to Environment Canada in January 2009. This was the first time that Environment Canada had been directly involved in the approval of a genetically engineered organism. Environment Canada was given the responsibility for assessing the environmental risks of the Enviropig™ because there are no specific regulations for biotechnology-produced animals in Canada.

In 2009 the University of Guelph had also submitted a notification to Health Canada to approve its Enviropig™ for human consumption (Mann, 2011). The University had not received a mandatory or acknowledged deadline for a decision (Mann, 2011). As of August 2012 Health Canada had not released a decision concerning the University's notification (the notification process is discussed further in Chapter 2).

There is no publicly available information about regulation or decisions regarding the human consumption of biotechnology-produced animals. One assumes that it will become available once a decision is made, but even that is not known. Due to the confidential nature of the submission of an application to Health Canada it was unknown whether Health Canada has received or has been working on similar applications. In the case of the Enviropig™ application the University of Guelph had released information that it had submitted an application to Health Canada (Mann, 2011). At time of writing, there was also no publicly-available information regarding the depth, or scientific accuracy of the information Health Canada used to inform its decisions, as well as any potential risks it might be investigating (Personal communication with Federal Employee; Health Canada. Food Directorate. Health Products and Food Branch, 2006; Health Canada 2006d; Health Canada 2011c).

It is possible that AquaBounty Technologies, Inc has submitted an application to Health Canada to approve its genetically engineered (GE) AquAdvantage® salmon for human consumption. The company developed the salmon at a research facility in Prince Edward Island (P.E.I.) using technology developed by scientists at Memorial University. The salmon have been genetically engineered with the intent to grow faster than their natural counterpart (AquaBounty Technologies Inc, 2012a). As of December 2012, AquaBounty Technologies, Inc. had not

released information on whether it has submitted an application to Canada's regulatory authorities to approve its salmon for human consumption.

Information is also unavailable regarding whether or not Health Canada has ever received an application to approve a cloned animal for human consumption. Cloned animals are produced through modern biotechnology and any food products from these animals would be classified as "novel foods" under Division 28, Part B, of the *Food and Drug Regulations*. The limited publicly-available information raises serious questions about transparency of Federal Government decisions regarding the Canadian food system (discussed further in Chapter 3.3.6).

The Boundaries of the Regulatory Framework

The *New Substance Notification Regulations* (NSNR) were created to address the potential risks to the Canadian environment and human health posed by the large scale (industrial) use of commercial chemicals. They were not developed for substances regulated under the *Food and Drugs Act* (Health Canada, 2010b). Since 2001 Health Canada has been in the process of developing new Environmental Assessment Regulations (EARs) to replace the NSNR with respect to new substances in products regulated under the *Food and Drugs Act* (Health Canada, 2010b). There is no indication when work on these EARs will be completed.

Current regulatory processes are based on substantial equivalence, are limited to assessing risks that are science-based and do not take into consideration any social, ethical or economic impacts that citizens might feel are critical to the debate on human consumption of biotechnology-produced animals. Regulatory departments do not conduct long term health or safety studies as "there is no current evidence to indicate that long term studies are needed to ensure the safety of foods produced using this technology" (Health Canada, 2006d). Canada also does not have a mandatory labeling standard for identifying whether foods contain products derived through modern biotechnology. As such, it is unknown whether, if approved, mandatory labeling would be implemented for food products that contain biotechnology-produced animals.

The Regulation of Food Products Derived through Modern Biotechnology

Food products derived through modern biotechnology do not readily fit within existing regulatory frameworks. This situation has created a need for regulations and guidelines to continuously be updated to take into account any new risks. This patchwork regulatory

framework continues to be tested as new food products derived through modern biotechnology enter the market and new risks are made apparent.

Regulatory processes to assess the risk of consuming food products are also product-based and do not examine whether any new risks are created through the process of biotechnology. At the time of the writing of this thesis it was unknown how, and if, policies and regulations will be updated to include the assessment of potential risks unique to consuming biotechnology-produced animals. For example, it was unknown how potential new risks concerning the health and safety aspects of consuming biotechnology-produced animals will be considered in Health Canada's safety assessment.

In short, technology is racing ahead of the Federal Government's ability or willingness to develop and or to share policies with the general public with respect to the introduction of novel foods into the Canadian food system.

Given that citizens may not know a food product has been approved for sale until it has already entered the market place, it is important to know who is making the decisions and how they are being made. As more biotechnology-produced animals near commercialization and regulations are being updated it is important to consider decision-making processes and the transparency of regulatory institutions and processes. A multitude of decisions will have to be made by the Canadian Federal Government regarding whether and how biotechnology-produced animals are to be approved for human consumption in Canada. Despite the magnitude of the decisions involved, the Federal Government is virtually silent with respect to how it will be addressing these issues.

1.1.2 Research Question, Academic Rationale and Conceptual Framework

To shed light on the above issues, this thesis considers the following question:

How transparent are the Federal Government's decision-making processes and institutions with respect to the human consumption of animals produced through biotechnology throughout the policy and decision-making process? If transparency is an issue, what are the barriers to achieving transparency and how might they be overcome?

Through an exploration of these questions the goal of this research project is to provide a timely study of the Federal Government's decision-making processes to determine the degree of transparency in a topic of notable public interest: the human consumption of biotechnology-produced animals

The transparency and accountability of decision-making processes and institutions are increasingly important as food products from biotechnology-produced animals are being considered for human consumption. This project highlights potential issues concerning transparency throughout the Federal Government's decision-making processes before policies are finalized. This is especially useful as Federal Government decisions regarding the human consumption of biotechnology-produced animals in the following months and years have the potential to revolutionize food systems on the national and international levels.

Defining Transparency in the Context of Food Democracy

Transparency "is widely associated with more accountable, legitimate, democratic and effective governance, partly based on an assumption that it can empower those at its receiving end" (Gupta, 2010a, p. 32). According to Aarti Gupta, a lecturer in International Environmental Politics "such associations and assumptions require much more sustained scrutiny" (Gupta 2010a, p. 32). Gupta noted "the embrace and institutionalization of transparency in specific instances plays out within a broader global governance context shaped by a liberal democratic push for individual liberty, choice and participation; but also by a neoliberal privileging of market-based solutions to environmental and social challenges and support for 'light touch' regulation of the private sector" (Gupta, 2010b, p. 6).

Transparency as a concept is subject to contested definitions. As its simplest, transparency is defined as the disclosure of information (Mol, 2010, p. 132). With regards to transparency in domestic policy, there are "wide variations in the ability of information disclosure to produce the outcomes it is supposed to achieve" (Haufler, 2010, p. 55). Director of Global Communities Living-Learning Program at University of Maryland, Virginia Haufler, has identified, as stated by Gupta, "various disfunctionalities of disclosure that pose hurdles to stakeholder empowerment or environmental improvements, including unreliable data, shirking of disclosure obligations, lack of capacity to interpret and use disclosed data or lack of civil society or other intermediaries to render disclosed information useful" (Gupta, 2010b, p.5). A reliance

on transparency as a tool of governance can also “be subverted in practice via the phenomenon of ‘drowning in disclosure’ or provision of too much information, where the relevant is buried in the irrelevant and hard to find, if provided at all” (Gupta, 2010a, p. 39). A central aspect of governance by disclose also raises the question of transparency: for whom and to what end (Gupta, 2010a, p. 46).

Often evoked goals of transparency also include “empowering the weak and holding accountable the powerful” (Gupta, 2010b, p. 1). Whether transparency furthers such goals is under-scrutinized (Gupta, 2010b, p.1). As well, the ideal of transparency often remains contested (Gupta, 2010b, p. 7). Haufler wrote “As Fenster argued ‘Transparency theory’s flaws result from a simplistic model of linear communication that assume that information, once set free from the state that creates it, will produce an informed, engaged public that will hold officials accountable’”(2010, p. 55).

Haufler also noted “Democracy itself is founded on the principle of transparent governance” (2010, p. 55). As stated by Chair and professor, Director of Wageningen School of Social Sciences at Wageningen University, Arthur P.J. Mol, the concepts of transparency, democracy and participation are related to each other in environmental politics and governance, although the three do not always mutually strengthen each other (2010, p. 133).

The formal institutional notion of transparency is not sufficient within the context of food democracy. The paper expands the formal institutional notion of transparency in response to public democracy and issues of governance. The essential elements of transparency being examined for this research paper include: the disclosure of information; the outcomes produced by the disclosure (or lack of disclosure) of information; the capacity of interested parties to interpret and utilize disclosed information; whether public officials are being held accountable; connections between participation, transparency, and democracy; whether opportunities are provided for interested parties to provide feedback, analysis and system improvement; the accountability, legitimacy, democratic nature, and effectiveness of governance; whether transparency initiatives empower those at the receiving end and; hurdles to stakeholder empowerment. These different aspects of transparency as understood in the context of food democracy will be explored in this thesis. Of specific concern here is the Canadian federal government’s regulatory and policy approach regarding biotechnology-produced animals.

Without transparency, Canadians collectively have a limited ability to hold decision-makers accountable to ensure both food security and food democracy. Food policy analyst Tim Lang (1999) referred to food democracy as “the demand for greater access and collective benefit from the food system” (p. 218). Environmental policy professor, Neva Hassanein, (2003) noted “food democracy is a method for making choices when values and interests come into conflict and when the consequences of decisions are uncertain” (p. 83). Hassanein argues that “all members of an agro-food system have equal and effective opportunities for participation in shaping that system, as well as knowledge about the relevant alternative ways of designing and operating the system” (2003 p. 83) and that “citizens having the power to determine agro-food policies and practices locally, regionally, nationally, and globally” (2003 p. 79).

Advocates of food democracy seek to expose and challenge any antidemocratic forces that control the agro-food system. The term food democracy also implies that the prevailing economic rules and regulations should encourage communities to “safeguard the soil, water, and wildlife on which all our lives and futures depend (Small Planet Institute, 2012).

Transparency, in a democratic government and country such as Canada, implies accountability. Transparency provides assurance to citizens and other affected stakeholders that powerful actors, such as governments or corporations can be held accountable (Fuchs & Clapp, 2009 p. 93). Transparent decision-making allows citizens to hold public officials accountable by making judgments about the effectiveness of their government. Transparency provides a means for governments to demonstrate to the public that they are spending money wisely and making decisions that ensure the safety and protection of its citizens (Right to Know Community, 2008 p. 2). Fund and Weil argue that transparency can help citizens understand harms and risks to individuals and protect themselves (2010 p. 108). Further, transparency can be used to press organizations, including national governments and corporations, to behave in more socially responsible ways and decreases opportunities for authorities to abuse the system in their own interest (Fung & Weil, 2010 p. 108).

An informed public is essential to democracy and can help to create a more effective, accountable government. Governments “need to provide information to make their own activities more transparent to citizens, in order to promote accountability and to enable citizens to determine how well the political system and civil society is functioning” (MacKinnon et al. 2003 p. xii). Transparency is essential if all affected stakeholders are to make informed decisions; in

other words, it “is based on the notion that stakeholders would make different choices if they had less complete information” (Dingwerth & Eichinger, 2010, p. 79). As well, “transparency will only work when the quality and reliability of information is guarded and guaranteed” (Mol 2010, p. 138).

Effective transparency goes beyond disclosing documents through Freedom of Information legislation and the Access to Information Act, where it is often up to the citizens to independently obtain information through a formal request. It also goes beyond focusing primarily on accountability (Fung & Weil, 2010, p. 106). As stated in *The Right to Know Community, Moving towards a 21st century right to know agenda: Recommendations to President-Elect Obama and Congress* (2008)

Effective transparency means that the public has access to accurate information in a timely manner....No one policy change or action will suddenly make government completely transparent. The solution is not as simple as instituting guidance to agencies to disclose as much information as possible under Freedom of Information Act requests, although most certainly that must be done. (p. 2)

Furthermore, transparency is considered as being most effective when it is part of

A disciplined process that sets priorities, assesses probable impacts of alternative or complementary government measures, minimizes unintended consequences, and generates feedback, analysis, and system improvement over time. (Graham, Weil & Fung, 2007, p. 181)

The Federal Government cannot be held accountable if its decision-making processes lack transparency. Druke notes that accountability is the fundamental principle of a transparent society and a cornerstone of modern democracy (2007 p. 60). Kernaghan and Siegel (1995) suggest that accountability is concerned with “the legal, institutional and procedural means by which bureaucrats can be obliged to answer for their actions” (p. 314) and that it is one of “the most important and most contentious of the traditional public service values” (p. 668).

An examination of the degree of transparency in the Canadian Federal Government’s decision-making processes and institutions regarding the Enviropig™ and AquAdvantage® Salmon provides a good indication of the current direction the Government is taking concerning the human consumption of foods produced through modern biotechnology. It also offers an understanding of the transparency, or lack thereof, in Federal Government decision-making processes in areas that are of significant public concern.

Graham et al. (2007) stated that transparency benefits associated with advancing technologies are not automatic and depend heavily on the willingness of information users, disclosures, and government officials to assume new responsibilities (p. 165). The way the Canadian Government has addressed (or failed to address) foods produced through modern biotechnology (GE foods) has resulted in non-government organizations (NGOs), including the Canadian Biotech Advisory Network (CBAN), and MPs, including Fisheries and Oceans Critic Fin Donnelly (NDP), becoming increasingly concerned over the lack of accountability and transparency (discussed further in chapters 3 and 4).

Canada has not introduced unique regulations to specifically deal with the socio-ecological, health and policy implications of the human consumption of products developed through modern biotechnology. Canadian citizens may want to know more about the risks being considered in regulatory decision-making processes regarding the consumption of biotechnology-produced animals and how Federal Government institutions are evaluating these risks during decision-making processes.

Exploring the state of food democracy through the decision-making processes provides information on the direction the Federal Government is taking that goes beyond conventional notions of transparency held by a representative democracy. The specific issues with food adds a layer of complexity in terms of transparency as some stakeholders may feel they should have a bigger role in shaping their food systems, particularly considering new food products derived through advancing technologies that have never been introduced into the food system are nearing the stage of commercialization.

It should be noted that the market for the human consumption of biotechnology-produced animals is not a foregone conclusion. In April of 2012, the University of Guelph began closing down its active research on the Enviropig™. The hog industry group, Ontario Pork, the largest contributor to the project, had decided to redirect its funding away from research on the Enviropig™ (Leung, 2012). The Enviropig™ research had received contributions around \$1.2-million from Ontario Pork over the past decade. Leung (2012) also wrote that Bona Hunt, a spokesperson for University of Guelph, had said the University would keep active the applications the University had submitted to various Governments to approve the animal for human consumption until the University decides otherwise, or a regulatory decision is made. The University is preserving the genetic material of the Enviropig™ in long-term storage and stated it

will continue to research the animal and is looking for another sponsor or organization that would be willing to adopt the technology (Leung, 2012).

Conceptual Framework: Food Democracy and Transparency

As stated, transparency as a concept is subject to contested definitions. Food democracy provides a lens for viewing transparency that goes beyond the formal institutional definition to include considerations such as inclusiveness and empowerment. This research project explores the issue of food democracy through an examination of the degree of transparency in the Canadian Federal Government's decision-making with respect to the human consumption of biotechnology-produced animals. The difference between the formal institutional concepts of transparency and what is needed to ensure food democracy highlights specific issues that surround decision-making concerning the food system that add a layer of complexity in terms of transparency. Even if decision-making were transparent in the traditional formal sense, the Federal Government might still be at odds with expectations from stakeholders who believe the issue of food is such an important and complex one that more transparency than is formally required is necessary for decision-making. Stakeholders may in fact be demanding increasing amounts of transparency that might very well be at odds with the current Federal Government approach to questions of transparency and accountability.

Rationale for Choosing the Canadian Federal Government as Key Actor

The Federal Government was chosen as the focus of this thesis because the international arena shapes the decision-making arena of major players in the agro-food industry. The international trade of foods produced through biotechnology is being negotiated extensively at the international level. International agreements signed by the Federal Government such as the North American Free Trade Agreement can overrule policies made at municipal, provincial and Federal levels (NAFTA Secretariat, 2012). The role of Federal-provincial relations will be examined because the way in which a jurisdiction is split can affect transparency unless there is good coordination.

The thesis is focused on Canada, a hub for biotechnology research. Canada's research community has developed both the Enviropig™ and AquAdvantage® salmon. Canada has the

potential to pave the way for both developing and creating regulations for biotechnology-produced animals.

The Canadian Federal Government is also the focus for this thesis due to its controversial history of decision-making with regard to food products derived through modern biotechnology (discussed further in Chapter 3). In addition, Canada is a significant player in the sector, globally speaking, more for its adoption, than for its development, of biotechnology (Pechlaner & Otero, 2008 p. 360). Lastly, in regards to the regulation of animal biotechnology because there is currently no definitive, comprehensive Canadian position, there is much room for analysis.

In the international arena, Canada is a strong voice advocating for biotechnology. In 2011, according to the *International Service for the Acquisition of Agri-biotech Applications*, twenty-nine countries had elected to grow crops derived through modern biotechnology. Canada ranked fifth in the area of land planted with biotechnology crops, as seen in Table 1.1. (James, 2011). The gap between the top five producers of biotechnology and the rest of the world in regard to growing biotechnology crops is clearly evident, as is Canada's place concerning biotechnology in the international arena.

Table 1.1. Global Area of Biotech Crops in 2011 by Country

Rank	Country	Area(million hectares)	Biotech Crops
1	USA	69	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash
2	Brazil	30.3	Soybean, Maize, Cotton
3	Argentina	23.7	Soybean, Maize, Cotton
4	India	10.6	Cotton
5	Canada	10.4	Canola, Maize, Soybean, sugar beet
6	China	3.9	Cotton, papaya, poplar, tomato, sweet pepper
12	Australia	0.7	Maize
27	Sweden	<0.1	Potato
28	Costa Rica	<0.1	Cotton, soybean
29	Germany	<0.1	Potato

Source: Adapted from James (2011)

1.1.3. Assumptions, Limitations and Boundaries

An assumption of this research project is that food policies surrounding controversial issues should be governed in a transparent manner consistent with that of a democratic polity. This

research project also assumes that food democracy is a valid concept when examining a country's approach to a controversial food topic. The focus for this research project is on contemporary events in order to build on previous work. This thesis builds on work on the governance of genetically engineered foods in Canada at the Federal level that the researcher completed for her undergraduate degree through the University of Waterloo.

Information on the Canadian Food Inspection Agency (CFIA) website concerning novel feed from biotechnology derived animals does not say how Canadian's would be informed if this type of feed had been approved, or was going through the approval process (CFIA, 2006). The CFIA website does have a list of approved novel feeds from PNTs, last updated in April 2012 (CFIA, 2012c). Information can also be found on applications concerning novel feeds derived from PNTs through the CFIA's voluntary notice of submission project (CFIA, 2012b). The assessment of novel feed from biotechnology derived animals is beyond the scope of this thesis.

Although the researcher has done her best to control for biases, they need to be acknowledged. In March of 2012, while working on this research paper, the researcher signed a petition that was distributed by the Canadian Biotechnology Action Network (CBAN) and directed at the University of Guelph entitled "Stop the Genetically Modified 'Enviropig™'" The researcher also signed CBAN petitions regarding GE alfalfa and GE salmon. The researcher is also part of a Toronto-based food action and awareness initiative that formed in April of 2012. Although the researcher has a position, it has not prevented her from being open to exploring other points of views.

1.2. Thesis Structure

1.2.1. Methodology

This thesis uses a five-part methodology in order to effectively answer the research question. A combination of methods includes a grounded, inductive approach. First, government structures are considered with respect to their public accountability concerning the human consumption of biotechnology-produced foods. This analysis offers an understanding of transparency in the traditional formal institutional sense and sheds light on transparency within the Federal Government's structures and institutions. Second, the paper explores limitations to transparency that have arisen concerning the Federal Government's decision-making processes and

institutions with respect to foods derived through modern biotechnology. A historical analysis reveals an enduring lack of transparency and accountability regarding the Federal Government's decision-making processes and institutions for foods derived through modern biotechnology; this situation has continued to the present day throughout both Conservative and Liberal governing mandates. Third, interviews were undertaken with key stakeholders. A snowball sampling approach was used to identify stakeholders. A grounded approach was used to identify major issues and themes that emerged from those interviews with respect to transparency and the implications of consuming biotechnology-produced animals. Fourth, a comparative assessment was made between limitations to transparency raised in the interviews and throughout the literature. It allowed for an examination of current issues surrounding the human consumption of biotechnology-produced animals in order to assess and analyze the transparency of the Federal Government's decision-making processes and institutions, and to explore challenges and opportunities for increasing transparency. Lastly, the paper provides recommendations for future research.

Data Collection

Information about biotechnology-produced animals and transparency was gathered using multiple sources of evidence. According to Yin (2003), in his *Case Study Research: Design and Methods 3rd Edition*, this approach is often referred to as “triangulation” and allows for information to be cross-checked through a variety of sources (p. 97). The sources of evidence are: (1) literature produced by the agro-food industry and its critiques; (2) academic literature concerning the topics of genetically engineered (GE) foods, biotechnology-produced animals, transparency and Canada's policy-making structure; (3) Government publications and primary records and; (4) interviews with key-informants including scholars and Government officials. Information was collected through an examination of private and public websites and publications, by attending conferences, through academic and trade journals, Access to Information requests, academic papers and interviews.

Publications produced by the agro-food (biotechnology) industry as well as publications that critiqued the point of view of the agro-food industry were obtained to determine what information exists on biotechnology-produced animals and whether issues of transparency have arisen. This allowed for the identification of biotechnology-produced animals that are at or are

nearing commercialization both domestically and internationally. It also allowed for the identification of potential applications to assess a biotechnology-produced animal for human consumption through examining research and development projects concerning biotechnology-produced animals.

Federal Government documents including publications and primary records as well as Federal Government websites were examined to determine Canada's Federal policy-making structure in regard to the human consumption of biotechnology-produced animals. Looking at these documents allowed for the collection of information on what the Government is doing in terms of making the decision-making processes transparent. The research also examines what animals have gone through policy processes in Canada for other reasons, including environmental release, to shed light on potential applications. This allowed for an examination of how Canadian formal institutions have been used to raise awareness of issues of transparency and how biotechnology is promoted in Canada.

Interviews were undertaken with a spokesman from a large Canadian food distributing company, a consumer affairs reporter from a major news outlet, representatives of non-government organizations, scholars, elected officials and public servants at the federal level to gain an understanding of what key stakeholders identified as important themes and issues. This information was compared with the issues identified in the literature to see where they diverged or corresponded. The findings shed light on the transparency of the Federal Government's decision-making processes and institutions concerning foods products that are or contain biotechnology-produced animals.

Data Analysis

The grounded theory (GT) method developed by sociologists Glaser and Strauss was utilized for this paper to identify major themes in interviews. Glaser and Strauss's approach "showed us how to treat qualitative data as a serious source of scientifically derived knowledge about social and psychological processes" (Bernard, 2010, p. 267). The approach, which uses open-ended interviews, uncovers "many patterns the participant does not understand or is not aware of" (Glaser, 2002, p. 5).

As defined by Glaser (1992) coding is "conceptualizing data by the constant comparison of incident with incident, and incident with concept to emerge more categories and their

properties” (p. 38). Coding occurs in two stages: substantive (open) and theoretical. According to Glaser (1992) “open coding is the initial step of theoretical analysis that pertains to the initial discovery of categories and their properties” (p. 39). Following the direction of Glaser (1992), during open coding data is broken down into incidents and is closely examined and compared for similarities and differences (p. 39). For this paper, data from the interviews was simultaneously collected and analyzed. Transcripts were analyzed in sentences or groups of sentences that reflect single ideas. The data was analyzed for increasing levels of abstraction through the use of constant comparative procedures, through negative case analysis and through the researcher asking questions about her own data. Concepts were identified within the data. How the concepts might relate to larger more inclusive concepts, referred to as “categories” in the language of GT, was examined (Bernard, 2010, p. 271).

Categories concerning the interview data were identified and connected and a theory was formed to aid in answering the research question. Categories were based on all data collected through interviews, observations, and the researcher’s notes. Categories were linked together as they emerged in theoretical models around a central category (Bernard, 2010, p. 275). As stated by Glaser (1992) “open coding comes to an end when it yields a core category” (p. 39).

The coding stage is the “refitting and refinement of categories which integrate around emerging core” (Heath & Cowley, 2004, p. 146).

Common to all grounded theorists is the knowledge that one ceases the relentless pursuit of data when theoretical saturation is achieved: (1) no new or relevant data are emerging regarding a category (2) development of the category’s properties and dimensions can withstand variations in the context of the phenomenon, (3) the relationships amongst categories are well established (Morse, 1995). (Boychuk Duchscher & Morgan p. 610)

Through the emergence of categories and the core category the researcher identified barriers to transparency relevant to the research topic.

The researcher used this approach to develop major themes through interviews. These themes became the core of the final grounded theory. These themes were then compared with the limitations to transparency identified in the literature in order to answer the research question. This data was analyzed to identify any serious questions of transparency and serious concerns about the human consumption of biotechnology-produced animals. Collected data also was analyzed to determine any similarities and divergences among the literature produced by the agro-food industry, its critiques, academic literature, Federal Government documents, and

interviews. This analysis served to identify any lack of connection between what the Federal Government is doing, what it says it is doing, and the critiques of what it is doing. Any lack of connection helped to identify challenges and opportunities for transparency in the Federal Government's decision-making processes. It also allowed for the identification of any serious health or democratic issues.

1.2.2. Chapter Outlines

This thesis is structured into seven chapters.

Chapter one introduces the reader to the research project (i.e. the research question, rationale, boundaries, contributions and assumptions, and methodology).

Chapter two examines who in the Federal Government is making decisions concerning the human consumption of biotechnology-produced animals and how these decision makers are held accountable.

Chapter three offers an overview of issues of transparency with respect to Federal policy-making processes for foods produced through modern biotechnology. It also provides background information and a linear progression on the creation and evolution of Federal Government policies that deal with the human consumption of biotechnology-produced animals, leading to the current situation.

Chapter four consists of primary research findings. It outlines the research approach taken to conduct interviews and discusses the emerging themes concerning transparency identified in the interviews through the use of the ground theory method.

Chapter five provides an analysis of the findings through comparing limitations to transparency raised by the interviewees with those identified by the literature review. It discusses current issues with biotechnology-produced animals that outline the decreasing transparency and accountability of the Canadian Government. It identifies the biggest institutional impediments to transparency.

Chapter six provides examples of existing and potential opportunities to increase transparency identified in interviews and through the literature.

Chapter seven concludes the thesis by providing a summary of the research project, contributions, and recommendations for future research.

Chapter 2: Canadian Public Policy and Public Administration in the Context of Biotechnology-Produced Animals

2.1. Introduction

The Canadian Federal Government is responsible for making policies and regulations with respect to the human consumption of biotechnology-produced animals. Decisions are made through both the elected and non-elected arms of the Federal Government. Federal Government institutions, non-government organizations (NGOs), private sector bodies, and media outlets can be utilized to ensure Federal Government transparency in decision-making. This chapter examines how the Federal Government is structured and held accountable with respect to making policies and regulations concerning the human consumption of biotechnology-produced animals.

2.2. Decision-Makers in the Federal Government

In order to untangle who is in charge of what decisions with respect to the human consumption of biotechnology-produced animals, it is necessary to explore the basic structures of decision-making and their impact on questions of transparency and accountability in this topic area.

2.2.1. Cabinet and Parliament: Elected Representatives Responsible for Biotechnology-Produced Animals

Canada has a centralized system of Federal Government concerning decision-making for the human consumption of biotechnology-produced animals. The elected arm of the Federal Government, beginning with the Prime Minister, the Cabinet, and the elected members of Parliament, are at the centre of policy-making. The Prime Minister can announce the policy of the Federal Government even if most or all of the Cabinet Ministers are opposed.

The Prime Minister determines the existence and responsibilities of all cabinet committees except for the Treasury Board. Cabinet committees help coordinate policies and programs, allocate human and financial resources, and control the bureaucracy. For example, with respect to food produced through biotechnology, the Cabinet Committee on Economic Prosperity and Sustainable Growth's role could include ensuring that policies were in line with Canada's long-term priorities and commitments.

House of Commons

Elected Members of Parliament (MP) in the House of Commons create, debate, and vote on bills and legislation concerning foods produced through modern biotechnology. For example, in 2009, Alex Atamanenko, MP for BC Southern Interior and the NDP Agriculture Critic at the time, introduced Private Members Bill C-474. The bill, which was defeated, called for amendments to the *Seed Regulations* “to require that an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted” (Bill C-474: An Act respecting the Seeds Regulations (analysis of potential harm), 2009).

The Senate and Senate Committees

The Senate reviews legislation, investigates national issues and represents regional, provincial and minority interests (Canada. Parliament, n.d.). Senate committees in the current session that could impact decision-making for the human consumption of biotechnology-produced animals include Fisheries and Oceans, Agriculture and Forestry, and Social Affairs, Science and Technology. The Senate and Senate Committees can play a role with respect to GMOs. However, it did not play an important role during the time frame under examination.

2.2.2. Public Service: Central Agencies and Line Departments in Charge of Regulatory Decision-Making concerning Biotechnology-produced animals

Central Agencies

Central agencies have a substantial amount of authority to intervene in and direct the activity of Federal Government departments (Kernaghan & Siegal, 1995, p. 197). The advice they provide to the Prime Minister, Cabinet, and Cabinet Committees can deal with the use of resources as well as policy direction. Central Agencies can also be used as a source to provide accountability in any decision-making process. They can be linked to departments and task forces through projects, initiatives and action plans.

There are four central agencies: Prime Minister’s Office; Privy Council Office; Department of Finance; and Treasury Board. They are all influential. If the United States approved a biotechnology-produced animal for human consumption, for example, the

Department of Finance might intervene in Canada's policy development process to streamline regulations with its largest trading partner.

Line Departments

Along with the elected arm of Federal Government, Health Canada; the Canadian Food Inspection Agency (CFIA); Environment Canada; and the Department of Fisheries and Oceans hold responsibility and authority regarding decision-making concerning the human consumption of biotechnology-produced animals. Each of these departments and agencies has its own role in enforcing, creating, or updating regulations and guidelines that pertain to these food products. They also feed information upwards to the executive arm of the Federal Government. Health Canada ensures the safety of foods derived from modern biotechnology before they enter the Canadian food system through a pre-market notification under the *Food and Drug Regulations* and an environmental assessment under the *Canadian Environmental Protection Act (1999)* (CEPA). Environment Canada assists Health Canada with the assessments and conducts environmental assessments under CEPA before a biotechnology-produced animal can be manufactured, sold, or imported into Canada. Health Canada shares responsibility with the CFIA for all federal food labeling policies under the *Food and Drugs Act*. The CFIA also inspects fish before they can be sold as food. The Department of Fisheries and Oceans administers the New Substance Notifications for biotechnology-produced fish and undertakes risk assessments. Table 2.1 provides a summary of the responsibilities of each department and agency. The roles of the departments and agency regarding biotechnology-produced animals will be discussed further in this section.

Table 2. 1. Responsible Department and Agencies for Food Products that contain Biotechnology-produced animals: for Human Consumption

Product Regulated: biotechnology-produced animal for human consumption		
Responsibility	Federal Department(s) and Agencies	Legislation
Pre-market notification	Food Directorate, Health Products and Food Branch (HPFB) of Health Canada	<i>Food and Drugs Act and Regulations</i>
Pre-market environmental safety assessment of new substances in products regulated by the <i>Food and Drugs Act</i>	Environmental Assessment Unit of the New Substance Assessment and Control Bureau in the Healthy Environments and Consumer Safety Branch of Health Canada (HECSB) (aided by Environment Canada)	<i>Canadian Environmental Protection Act 1999(CEPA 1999)</i> and <i>New Substance Notification Regulations (Organisms)(NSNR (Organisms))</i>
Pre-market environmental Assessment	Environmental Impact Initiative within the HPFB and HECSB of Health Canada (aided by Environment Canada)	Environmental Assessment Regulations (EARs) (proposed) under CEPA 1999 or the <i>Food and Drugs Act</i> (to replace NSNR (Organisms) for products under the <i>Food and Drugs Act</i>)
Develop federal food labeling policy and set standards related to health and safety issues	Health Canada	<i>Food and Drugs Act</i>
Non-safety related product labeling	Canadian Food Inspection Agency (CFIA)	<i>Food and Drugs Act</i>
Labeling (Packaging, labeling and advertising of foods, inspection and enforcement)	CFIA	<i>Consumer Packaging and Labeling Act</i>
Animal Health	CFIA	Health of Animals Act and Regulations

Source: adapted from CFIA (2012e)

Table 2. 2. Responsible Department and Agencies for Food Products that contain Biotechnology-Produced Animals: for Manufacture, Import or Sale

Product Regulated: biotechnology-produced animal for manufacture, import or sale		
Responsibility	Federal Department(s) and Agencies	Legislation
Pre-market environmental assessment	Environment Canada, Health Canada	CEPA 1999, NSNR (Organisms)
Animal Health	CFIA (aids Environment Canada)	Health of Animals Act and Regulations

Source: adapted from CFIA (2012e)

Table 2. 3. Responsible Department and Agencies with direct Decision-Making Responsibilities regarding Food Products that contain Biotechnology-produced Aquatic Organisms for Commercial Purposes

Product Regulated: biotechnology-produced aquatic organisms for commercial purposes		
Responsibility	Federal Department(s) and Agencies	Legislation
Administer the NSNR for biotechnology-produced fish	Fisheries and Oceans	CEPA 1999, NSNR (Organisms)
Undertake risk assessments	Fisheries and Oceans	CEPA 1999, NSNR (Organisms)
New Substance Notification for fish products of biotechnology (<i>under development</i>)	Fisheries and Oceans	Fisheries Act and Regulations
Provide guidelines for transgenic aquatic organisms (i.e. potential environmental release) (<i>under development</i>)	Fisheries and Oceans	Fisheries Act and Regulations
Notification and compliance with the NSNR under CEPA 1999	Fisheries and Oceans / Environment Canada	CEPA 1999, NSNR (Organisms)
Approve Fish for use as a food (Fish Inspection Program)	CFIA	<i>Food and Drugs Act</i>

Source: adapted from CFIA (2012e)

Pre-market Notification under Food and Drug Regulations

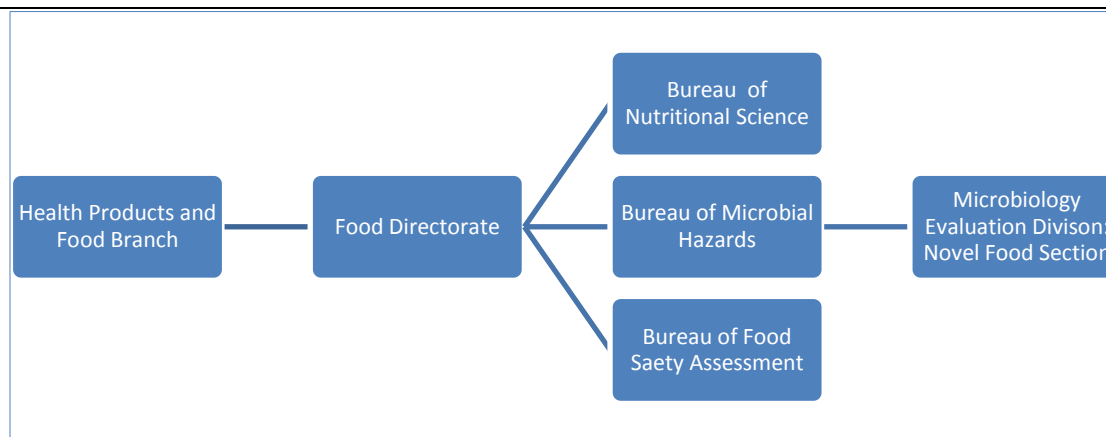
Health Canada is responsible for ensuring that foods derived from biotechnology-produced animals are safe before they enter the Canadian food system. Prior to the marketing, sale, or advertising of these food products the company that wants to sell the product must follow a mandatory pre-market notification procedure described under Division 28 of the *Food and Drug Regulation*.²

Under Health Canada’s Health Products and Food Branch (HPFB), the Novel Foods Section (formally the Office of Food Biotechnology) within the Bureau of Microbial Hazards’ Microbiology Evaluation Division is the coordinating office for processing the pre-market notifications. The Novel Foods Section distributes material submitted with the notifications to relevant Food Directorate bureaus for review, specifically the Bureau of Chemical Safety, the Bureau of Microbial Hazards, and the Bureau of Nutritional Sciences (Health Canada, 2006f). If evaluators consider the food product as novel under section B.28.001 of the *Food and Drug*

² The Food and Drug Regulations can be found on the Department of Justice Canada website

Regulations, a safety assessment is conducted as outlined in the *Guidelines for the Safety Assessment of Novel Foods* (Health Canada, 2006f; Food Directorate Health Products and Food Branch, 2006). Figure 2.1. outlines the organizational structure of these entities.

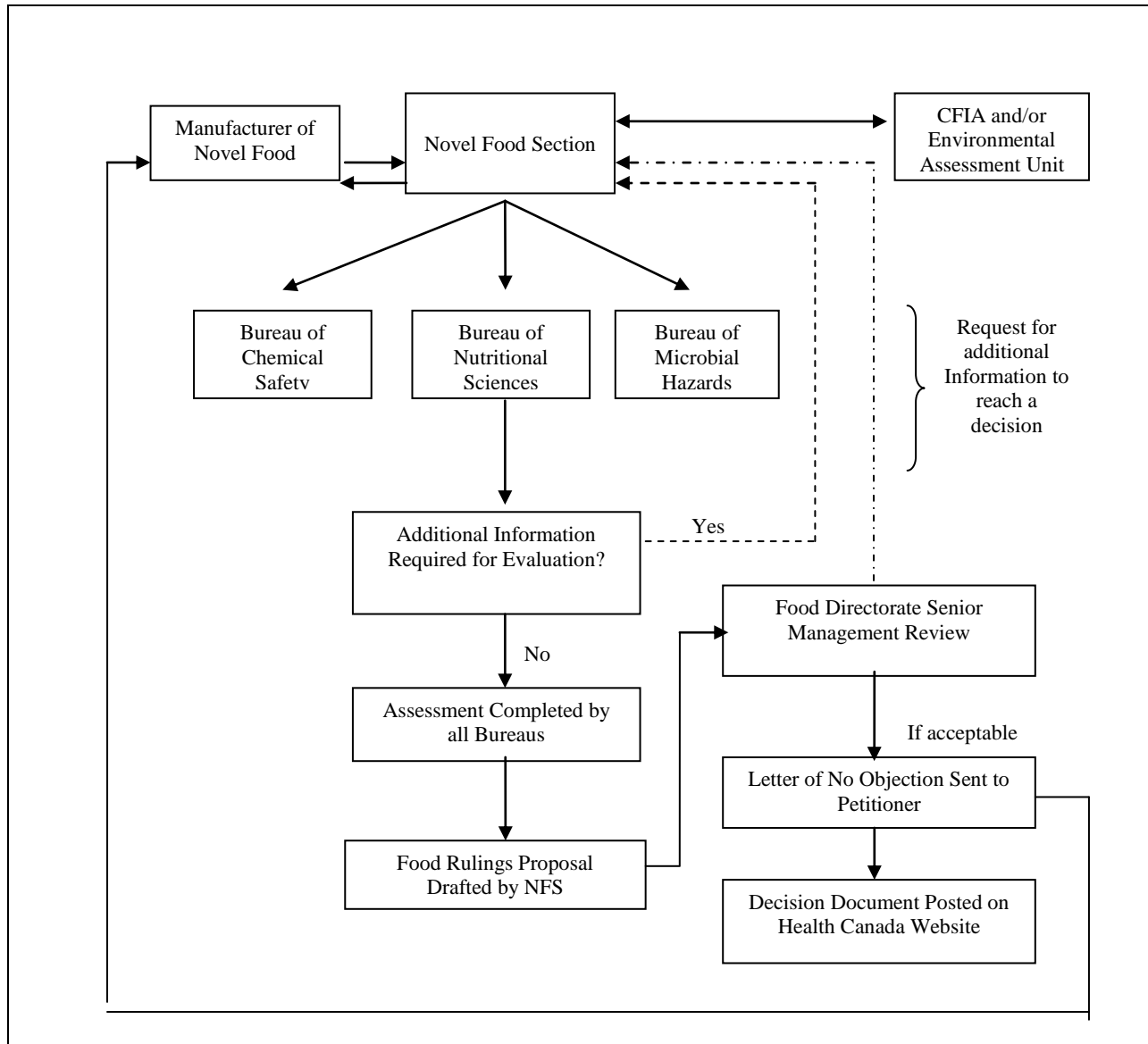
Figure 2. 1. Health Canada’s Organizational Structure concerning the Assessment of the Safety of Novel Foods



Source: Health Canada (2006g)

If no health risks associated with the consumption of the food product in question are found through the safety assessment (evaluators can make requests for additional information from the applicant) “a proposal to permit the sale of the novel food is drafted and presented to the Food Rulings Committee”(Health Canada, 2006f). The Committee is chaired by the Director General of the Food Directorate and includes senior managers of Food Directorate and representatives from the Canadian Food Inspection Agency which enforces Health Canada's decision (Health Canada, 2002). If the proposal is accepted the company is given written notification by the Director General that Health Canada has no objection to the sale of the novel food (Health Canada, 2002, Health Canada, 2006f). A decision document “describing the novel food and summarizing the safety information used to determine its safety as a food is posted on the *Novel Foods and Ingredients page* of Health Canada's Web site” (Health Canada, 2005b). Figure 2.2. outlines how a novel food notification is processed.

Figure 2. 2. Processing a Novel Food Notification/Submission in the Food Directorate



Source: Health Canada (2006g)

New Substance Notification Regulations under the Canadian Environmental Protection Act (1999)

Health Canada ensures the safety of food products derived through modern biotechnology before they enter the Canadian food system through pre-market notification under the *Food and Drug Regulations* described above. Manufactures or importers of these food products also have to submit notification under the *New Substance Notification Regulations* (NSNR) and the enabling

statutory authority of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) in order that an environmental assessment may be conducted (Health Canada, 2010b). The NSNR applies to products not regulated under other Federal legislation. The NSNR were not developed for substances regulated under the *Food and Drugs Act*. As stated on Health Canada's website the NSNR

were developed with industrial substances in mind, such as floor cleaners and fire retardants ...some substances regulated under the *Food and Drugs Act* have unique properties and exposure patterns that require a different approach to environmental assessment than what is currently required under the *New Substance Notification Regulations*. (Health Canada, 2011c)

A 2001 agreement between Environment Canada and Health Canada gave the latter responsibility to conduct the full assessment of these substances. Since 2001, Health Canada has been in the process of developing new Environmental Assessment Regulations (EARs) to replace the NSNR with respect to new substances in products regulated under the *Food and Drugs Act*, including foods that are or contain biotechnology-produced animals (Health Canada, 2010d). As of December 2012 the regulations have not been completed.

Regulating Biotechnology-produced animals for Manufacture, Import or Sale

A safety assessment under the *New Substance Notification Regulations (Organisms)* must also be completed before a biotechnology-produced animal can be manufactured, imported or sold in Canada. The producer or manufacturer must notify Environment Canada "so that the animal undergoes a safety assessment for potential impacts to the Environment" (Canadian Food Inspection Agency, 2012a). The assessments are co-administered by Environment Canada and Health Canada under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) and the *New Substance Notification Regulations (Organisms)*. The environmental aspects of the notification are evaluated by Environment Canada and the human health aspects are evaluated by Health Canada (CFIA, 2012a).

Applicants must support their application to manufacture, import, or sell to Canada any biotechnology-produced animals with technical documentation related to the animal's health. The CFIA gets consulted by Environment Canada regarding animal health matters during the process of assessing biotechnology-produced animals (CFIA 2012a). The CFIA gets its jurisdiction from the *Health of Animals Act*.

The Regulation of Biotechnology-produced Fish

The *New Substance Notification Regulations (Organisms)* NSNR (Organisms) also apply to any request to develop biotechnology-produced fish for commercial purposes. The Department of Fisheries and Oceans Canada (DFO) administers New Substance Notifications for fish products of biotechnology and undertakes risk assessments for these organisms (Fisheries and Oceans Canada, 2011). The DFO is working with Environment Canada to have any products that contain biotechnology-produced fish for commercial purposes, including manufacture, import and sale, assessed for notification and compliance with the NSNR under *CEPA 1999* (CFIA 2012a). The DFO is also developing regulations for biotechnology-produced aquatic organisms (Lupescu & Evans, 2012, p. 6). A timeline has not been given regarding when these regulations will be published (Lupescu & Evans, 2012, p. 6).

A biotechnology-produced fish would also have to meet the requirements of the CFIA's Fish Inspection Program before it can be approved for use as a food. The Inspection Program ensures that fish and seafood products meet food safety and quality standards. The CFIA is in the process of developing "new inspection tools, policies and compliance strategies...In order to effectively manage the introduction of approved novel food fish products to the Canadian marketplace" (CFIA, 2009b).

Labeling for foods that contain Biotechnology-produced Material

Health Canada shares the responsibility with the Canadian Food Inspection Agency (CFIA) for all food labeling policies under the *Food and Drugs Act*. Health Canada is responsible for developing policy and setting standards for required labeling related to health and safety issues (i.e. allergenicity, changes in nutritional composition). The CFIA is responsible for non-safety related product labeling (i.e. voluntary labeling and consumer fraud issues) and for applying Health Canada's policies and enforcing its regulations (CFIA, 2012d; Health Canada, 2005b).

In Canada mandatory food labels are required to address alterations in foods that pose health and safety risks that might be mitigated through labeling (CFIA, 2012d). Labels are not mandatory to identify a method of production, including modern gene technologies. As stated on the CFIA website "Voluntary labeling is permitted in order to provide consumers with information that is not related to the safety of the product" (CFIA, 2012d).

In April of 2004 a Canadian standard entitled *Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering* was implemented to address non-health and safety concerns (Health Canada, 2008). The voluntary standard refers to genetic engineering as “techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination” (Canadian General Standards Board, 2004, p. 2). The voluntary labeling standard was not intended to address health and safety concerns as these are already addressed by the *Food and Drugs Act and Regulations*. The standard specified voluntary regulations for products that were and were not products of genetic engineering with a 5% allowance of GE crops in food products not considered to be derived from genetic engineering (Canadian General Standards Board, 2004).

2.3. Mechanisms of Accountability

Federal Government institutions, non-government organizations (NGOs), private sector bodies, and media outlets can all serve to ensure Federal Government transparency in decision-making. Federal Government institutions include the Cabinet, the House of Commons, the Courts, the public service; regulatory agencies; non-departmental organizations and; advisory groups. NGOs, the private sector, members of academia, and members of the media also examine transparency in Federal Government decision-making and institutions regarding the human consumption of biotechnology-produced animals.

2.3.1. Federal Institutional Mechanisms

A number of Federal Government institutions could be mandated to enhance the transparency of policy-making processes and institutions with respect to the human consumption of biotechnology-produced animals through the introduction of legislation and enabling regulations. Federal Government institutional bodies within the elected and the non-elected arms of government can be utilized to ensure transparency with respect to decision-making regarding the human consumption of biotechnology-produced animals. Such instruments can be used to control or influence bureaucratic actions and hold decision-makers accountable.

Parliament and Accountability Mechanisms

The ability to hold the elected Federal Government accountable in order to ensure that food is traceable and that decisions are transparent depends extensively on governing structures beginning with the elected legislative arm. This is done through legislative procedures in the House of Commons, “watchdog” agencies, and legislative committees.

Legislative Procedures in the House of Commons

Proceedings in the House of Commons including motions, debates, order paper questions, and question periods provide opportunities for Member of Parliament (MP) to hold Federal Government accountable including Ministers, the Cabinet, Central Agencies, and the Prime Minister. For example, in 2011, Fin Donnelly, MP for New Westminster—Coquitlam and the NDP Fisheries and Oceans Critic, tabled a motion (M-648) “asking for transparency and more study before genetically modified (GM) Atlantic salmon are approved for human consumption” (CBAN, 2011a). The motion did not pass.

Ministers are also answerable to the House of Commons for the policy and conduct of the Cabinet as a whole. They “are expected to take responsibility for, and defend, all Cabinet decisions” (Parliament of Canada, 2010). Ministers and Ministers of State must also “strictly uphold the confidentiality of Cabinet decision-making” (Privy Council Office, 2011, p. 1).

Watchdog Agencies

The use of watchdog agencies such as ombudsmen and auditors also assist legislators in ensuring responsibility in Federal Government through controlling or influencing bureaucratic actions (Kernaghan & Siegal, 1995, p. 421). The Office of the Auditor General of Canada, the Information Commissioner, and the Public Service Commissioner are three such agencies that can be used to foster transparency and accountability in federal policy-making processes and institutions.

The Office of the Auditor General of Canada

The Office of the Auditor General reports directly to Parliament and “provides objective information, advice, and assurance that legislatures can draw on in their scrutiny of Federal Government spending and performance” (Office of the Auditor General of Canada, 2007). The only other Federal watchdog agency that reports in this manner, instead of through a Minister, is

the Official Languages Commissioner (Kernaghan & Siegal, 1995, p. 423). The Auditor General's audit findings and annual reports to Parliament can be widely publicized in the media (Kernaghan & Siegal, 1995, pp. 423, 424). Recent transparency and accountability issues that have been raised by the Auditor General show that a lack of accountability with respect to GE foods is not without precedent. Such examples include the ongoing controversy surrounding the Department of National Defense over the cost of purchasing F-35 stealth fighter jets and inappropriate spending by Conservative Cabinet Minister Tony Clement in choosing which projects were selected for the multi-million dollar G8 legacy fund (Berthiaume, 2012; Smith, 2012). In 1995 amendments made to the *Auditor General Act* gave the Auditor General's Office an environmental and sustainable development mandate. The amendments, as directly stated on the Auditor General's Office website

- *created the position of Commissioner of the Environment and Sustainable Development within the Office of the Auditor General of Canada, giving the Commissioner specific monitoring and reporting duties, on the Auditor General's behalf;*
- *added environmental impact to what the Auditor General takes into account when determining what to report to the House of Commons;*
- *required federal departments and agencies to prepare sustainable development strategies and update them every three years; and*
- *authorized the Auditor General to receive petitions on environmental and sustainable development matters and required ministers to respond to them.* (Office of the Auditor General of Canada, 2012)

The Commissioner of the Environment and Sustainable Development reports to Parliament on behalf of the Auditor General “on the environmental petitions process, sustainable development strategies, and any other matters that the Commissioner believes should be brought to its attention” (Office of the Auditor General of Canada, 2007b).

It is part of the Commissioner's responsibilities to monitor departmental and agency responses to petitions. The Commissioner of the Environment and Sustainable Development “monitors the status of these petitions and the Government's response to them” (CFIA, 2012g) and “makes sure that the questions that Canadians pose and the issues that they raise are addressed by Federal ministers and their departments” (Commissioner of the Environment and Sustainable Development, 2001, p. 1). Former Commissioner of the Environment and Sustainable Development, Johanne Gelinis stated

Canadians have a fundamental right to know what their Government is doing to protect the environment and promote sustainable development. Petitions can provide them with this information. (Commissioner of the Environment and Sustainable Development, 2002, p. 3)

A representative from the Office of the Auditor General of Canada said that petitions play an important role in the overall audit planning process (OAG representative, personal communications, May 2012). Audit teams across the office review petitions and petition responses when they are preparing their long-term audit plans of departments and agencies and when they are embarking on individual performance audits (OAG representative, personal communications, May 2012). In some cases the Office will audit issues raised by petitioners and commitments made by ministers in their responses to petitions. In 2008–09 for example, the Office audited departmental progress related to the development of the Air Quality Health Index. The results of this work were reported to Parliament in the CESD's Status Report in March 2009 (Office of the Auditor General of Canada, 2009, p. 33)

The Auditor General's website also has a petitions catalogue that includes the full text of most petitions and Federal Government responses (Office of the Auditor General of Canada, 2010). Some departments and agencies, including the CFIA, post these responses on their websites (CFIA, 2012g).

As will be discussed further in Chapter 3, the petitions process has been used several times to shed light on issues of transparency and accountability regarding decision-making surrounding GE Foods. For example Greenpeace submitted a petition on Genetically Engineered fish in 2001 and a follow-up petition on genetically engineered fish in 2003. Government responses to these petitions were audited and findings were included in the *2004 Report of the Commissioner of the Environment and Sustainable Development* as well as the *2008 March Status Report of the Commissioner of the Environment and Sustainable Development* (Commissioner of the Environment and Sustainable Development, 2004a; Commissioner of the Environment and Sustainable Development, 2008). The purpose of the audits was to verify whether the Department of Fisheries and Oceans was making progress in developing regulations and conducting research to strengthen its risk assessment in support of regulations for genetically engineered fish.

In the follow-up audit of DFO's 2002 response for petition 38A on Genetically Engineered Fish, the Commissioner of the Environment and Sustainable Development set out to determine whether the department was making progress in developing specific regulations for transgenic fish. It found that the department had not followed through with its commitment as regulations had not been finalized. The 2004 report noted that all timelines set by the Fisheries and Oceans Department for completing regulations had been missed and included an insert on the timelines that had been set by the Department (Commissioner of the Environment and Sustainable Development, 2004a; Commissioner of the Environment and Sustainable Development, 2004b). An employee from the Office of the Auditor General of Canada also stated

it is recognized that having the NSNR as a catch all for innovative organisms is not appropriate. The government has acknowledged that departments are best placed to develop and administer regulations that are within their area of expertise. For GE fish this would be DFO. As we noted in our audit, 'The Department has the expertise to deal with fish and other aquatic organisms and is therefore seen by the government as best placed to manage a regulatory system geared specifically to meeting the complex challenges associated with GE fish'. (OAG representative, personal communications, May 2012)

The petitions and follow-up audits draw attention to the need for regulations for biotechnology-produced animals and for regulatory oversight. As of December 2012 unique regulations specifically designed for biotechnology-produced animals, including fish, have not been developed.

The Information Commissioner

Residents of Canada can also submit a request for information through the *Access to Information Act*. The Office of the Information Commissioner of Canada is a watchdog agency that administers the *Access to Information Act* by investigating complaints against denial of access to government information. If an Access to Information (ATI) request is submitted concerning the decision-making processes and institutions regarding biotechnology-produced animals, the person who made the submission can complain to this Office if they feel that information was being withheld without a valid reason.

The Public Service Commissioner

The Public Service Commission is another important watchdog agency serving Parliament “as the guardian of the merit principle in human resource management” (Kernaghan & Siegal, 1995, p. 423). If there were questions surrounding decision-makers that had authority over decisions being made regarding biotechnology-produced animals and conflicts of interest, political interferences, or political neutrality, the Public Service Commission would look into the matter. Both the Office of the Information Commissioner and the Public Service Commissioner report to Parliament through the Department of Justice (Kernaghan & Siegal, 1995, p. 421).

Parliamentary Committees

Parliamentary committees are the third major means by which the legislature can exercise control or influence over the bureaucracy and foster transparency in decision-making. Special, joint, standing and legislative committees can all serve to foster transparency in decision-making processes concerning foods produced through modern biotechnology. For example both the Standing Committee on Health as well as the Standing Committee on Agriculture and Agri-Food has been used in the past to study the issue of biotechnology in Canada (as discussed in Chapter 3). The Standing Joint Committee for the Scrutiny of Regulations can also be used to foster transparency in policy-making. Any regulations being updated or created, including the proposed Environmental Assessment Regulations for new substances and products regulated under the *Food and Drugs Acts* would be assessed by this Committee.

Federal Legislative Acts

The Federal Government has developed and enacted legislation to foster transparency in decision-making. Departments and agencies must comply with the legislation. Some legislation specifically measures the accountability of decision-makers; other acts measure how accountable decision-makers are to society at large (i.e. sustainability). Examples include the *Federal Accountability Act* enacted in 2006 and the 2007 *Public Servants Disclosure Protection Act* (PSDPA). Both Acts, among other things, attempt to increase protection for whistleblowers. Another act that can foster transparency is the 2008 *Federal Sustainable Development Act* (FSDA). This Act provides the legal framework for the Government of Canada to develop and implement “a Federal Sustainable Development Strategy [FSDS] that will make environmental

decision-making more transparent and accountable to Parliament” (Federal Sustainable Development Act, 2008). A requirement of the Act is that “Federal Government departments and agencies develop sustainable development strategies to support the FSDS” (Health Canada, 2012b). Acts can also followed by or have companion actions plans that include supporting policy, benchmarks, and other non-legislative measures. Whether responses to these Acts have increased transparency in decision-making regarding biotechnology-produced animals will be explored in this research paper.

Federal Consultations, Departments and Agencies

A mandatory component of a policy or regulation-making process is consultation. Information on past, upcoming or ongoing consultations can be found through the Government of Canada’s *Consulting with Canadians* website (Government of Canada, 2011a), as well as through the Federal Government’s *Canadian Gazette* website (Government of Canada, 2012b). The Federal Government has also created the website, BioPortal.gc.ca as “your window to biotechnology @ the Federal Government” (Government of Canada, 2012a). Under the heading “about this site” the website states

As part of their work, the departments and agencies of the Government provide a vast amount of online information about biotechnology. The BioPortal is a tool to help you locate information on biotechnology from these different Federal departments and agencies. (Government of Canada, 2005a)

Departments also undertake initiatives to inform interested parties about upcoming or ongoing consultations. For example Health Canada provides information about ongoing regulatory initiatives on the Public Involvement section of its website (Health Canada, 2012g).

Consultations that have taken place concerning regulation and policy-making that apply to the human consumption of biotechnology-produced animals are discussed in Chapter 3 and 4.

Federal departments and agencies can have specific offices and divisions tasked with examining issues of transparency. An example is the Food and Drugs Act Liaisons Office launched in March 2008 “to improve relations between external stakeholders and representatives of Health Canada, as well as to increase the openness and transparency in the regulatory process” (Health Canada, 2012c). The office is listed as “an impartial and confidential resource for individuals, business and organizations when they experience problems with how Health Canada

administers the *Food and Drugs Act*” (Health Canada, 2012c). The degree of impartiality, however, depends on the lens used by the observer and their perceptions of the validity and comprehensiveness of the literature presented.

The Public Service of Canada

Unlike Ministers, the Deputy Ministers and public servants are answerable, but not directly accountable, to Parliament and its committees for their decisions and recommendations (Kernaghan & Siegal, 1995, p. 419). Public servants are “directly accountable only to political and administrative superiors, to the courts, and to any internal Governmental authorities (e.g. central agencies) to which accountability is required by law or the administrative hierarchy” (Kernaghan & Siegal, 1995, p. 357). Although they are not directly accountable to the legislature, to pressure groups, to the news media, or to the general public, public servants “are generally required to explain their decisions and actions to those entities” (Kernaghan & Siegal, 1995, p. 357). If public servants felt that there were issues of transparency in decision-making processes concerning biotechnology-produced animals, they could also use these venues to shed light on issues concerning transparency and accountability.

Regulatory Agencies

Regulatory agencies are set up to enforce standards and legislation and have “the ability to make general rules or regulations, in the form of delegated legislation that have the force of law” (Economic Council of Canada, p. 56). Regulatory agencies have statutory authority, consist of a panel of members and are formed as a result of enabling legislation. Analysts Kernaghan and Siegel define a regulatory agency as a

statutory body charged with responsibility to administer, to fix, to establish, to control, or to regulate the economic, cultural, environmental, or social activity by regularized and established means in the public interest and in accordance with general policy guidelines specified by the government. This body is under the general direction of the legislature and a responsible minister with regard to policy matters but possesses relative autonomy in making individual decisions within those policy guidelines. (Kernaghan & Siegal, 1995, pp. 250, 251)

Some regulatory agencies also have direct administrative responsibility for operating programs. An example of a regulatory agency is the Canadian Food Inspection Agency (CFIA). The CFIA

both regulates and promotes food products produced through biotechnology (discussed further in chapter 3). This is rare in regulatory agencies because it can create a conflict of interest when an agency must operate a program affecting an industry while regulating that same industry.

Non-Departmental Organizations

Non-Departmental Organizations can also be used to foster transparency in Federal Government decision-making. These organizations can shed light on issues of uncertainty and provide advice and guidance to the Cabinet and individual ministers beyond that provided by public servants. These organizations “are more involved in advising, consulting, and/or researching than in implementing or doing” (Kernaghan & Siegal, 1995, p. 286). The accountability and success of these organizations can be judged through an examination of their membership, what advice is given, and whether and how the organization’s recommendations are considered during policy-making processes.

Royal commissions, task forces and advisory councils are non-departmental organizations. Royal commissions and task forces are temporary and are “constituted to investigate either specific incidents or general policy concerns and report to Government” (Kernaghan & Siegal, 1995, p. 287). Advisory councils are composed of private citizens and “created by the Government to provide an independent source of advice to a minister” (Kernaghan & Siegal, 1995, p. 296). Advisory councils sit on some boards such as the Canadian Food Inspection Agency.

The Federal Court of Canada

A matter of public policy can be challenged before the courts. The Federal Government has to defend that policy and in doing so the Government can provide transparency. During interviews for this paper a Liberal MP said “The court has the power to demand answers and the government has to talk to the court” (LMP-2). Another participant, a Green Party shadow cabinet member said going to court forces information to be made available (GP-1).

Advisory Groups

Advisory groups can be established by departments to provide advice and act as sounding boards to the branch and to other officials in the department. Advisory groups include working groups

and advisory committees, expert panels, roundtable forums and ministerial advisory boards. Advisory groups that have been established by the Health Products and Food Branch of Health Canada include the Environmental Assessment Working Group (EAWG), the Food Expert Advisory Committee (FEAC), and the Public Advisory Committee (PAC).

Working Groups and Advisory Committees

The Environmental Assessment Working Group (EAWG) meets three to four times a year. One of the purposes of the group is “to provide broad, strategic advice on policy, technical, operational and regulatory issues to Health Canada and Environment Canada on the development of appropriate Environmental Assessment Regulations for new substances contained in products regulated under the Food & Drugs Act” (Health Canada, 2010c). Whether the EAWG has increased accountability concerning the development of the EARs, which would apply to foods derived from biotechnology-produced animals, will be explored further through primary research findings in Chapter 4.

The Food Expert Advisory Committee (FEAC) meets twice a year and provides the Food Directorate with “broad expert strategic policy advice on the safety of food products” (Health Canada, 2011b). The impact of the FEAC on decision-making regarding biotechnology-produced animals will be pursued further in Chapter 4.

Health Canada’s Public Advisory Committee (PAC) was formed in 2002 “as a public/consumer involvement forum that advised on issues and initiatives as requested by the [Health Products and Food Branch of Health Canada]. It is a component of the Branch's strategy to increase transparency and public involvement through the consultation processes” (Health Canada, 2007). The PAC was shut down in 2004. What has replaced the committee with regards to the human consumption of biotechnology-produced animals will be explored through the following chapters.

Expert Panels

Independent expert panels can also be used by the Federal Government to provide expert advice to departments and agencies. The reports of these panels are often high profile and can shed light on the accountability of decision-makers and the decision-making process. For example in December of 1999 the Royal Society of Canada, Canada’s senior national body of distinguished

Canadian scientists and scholars, established the *Expert Panel on the Future of Food Biotechnology* at the request of Health Canada, the CFIA and Environment Canada. The Expert Panel was “to provide advice on the Canadian regulatory system and the scientific capacity the Federal Government requires in to the 21st century to ensure the safety of new food products being developed through biotechnology” (Royal Society of Canada, 2001, Prefatory Note). The Expert Panel released its findings in its report *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* in February of 2001.

When independent expert panels formed at the request of Federal Government do shed light on accountability, the panels’ findings might not lead to significant changes or can be overlooked. The Federal Government does not have to act on the findings. The Federal Government’s response to the Royal Society of Canada’s Expert Panel report was made through an Action Plan and series of progress reports, discussed further in Chapter 3 and 4.

Roundtable Forums

Roundtable forums are another type of advisory group that can aid in increasing transparency in decision-making. They allow interested parties to voice their opinions on the development of decision-making processes and whether decision-makers can be held accountable under the chosen decision-making process. The forums can be directed at citizens and/or industry representatives. For example the Consumer Association Roundtable was launched by Agriculture Minister Gerry Ritz in December 2010 to give consumers “an additional opportunity to raise concerns and discuss ways to further improve Canada's food safety system” (CFIA, 2010b). Another example is Agriculture and Agri-Food Canada’s Pork Value Chain Roundtable. The roundtable is “a collaborative effort between government and industry” and “provides an important platform for discussing ideas, priorities, and solutions and contributes to the success of Canada's pork industry” (AAFC, 2011).

Ministerial Advisory Boards

Ministerial advisory boards (MAB) can also be used to foster transparency in the decision-making process by providing advice to Ministers. For example in November 2010 Agriculture Minister Gerry Ritz appointed seven advisors to the MAB of the CFIA. This MAB “includes a diverse range of experts from the food, animal and plant health sectors who will advise the

Minister on food safety and other issues related to the CFIA's mandate" (CFIA, 2010a). Examining who was appointed to a MAB can aid in keeping ministers accountable.

2.3.2. Non - Governmental Organizations and Private Sector Bodies

Actors outside of the Federal Government can be used to hold decision-makers and decision-making processes accountable. Non-Governmental organizations (NGOs), members of academia, and the private sector exercise influence over both the development and implementation of public policies through lobbying. They can participate in Federal Government initiatives in order to provide advice, ask for information on decision-making or to question the accountability and transparency of a decision-making process. This can be done through communicating with public officials, speaking before committees as witnesses, boycotting a policy-making process, submitting ATI requests and filing petitions with the Auditor General's Office. These actors also participate in non-departmental organizations. Advisory bodies can also "be used for direct interaction between citizens and public officials, especially bureaucrats" (Kernaghan & Siegal, 1995, p. 500). In some cases participants are invited to join the undertaking, in other cases they can volunteer or apply to participate. The usual targets of their activity are Cabinet Ministers, public servants, and legislators (Kernaghan & Siegal, 1995, p. 479).

In addition to participating, or declining to participate, in Federal Government institutional processes, NGOs, academics, and members of the private sector can undertake their own initiatives to attempt to participate in decision-making. They can support House of Commons Bills and Motions and utilize avenues within and outside of Federal Government to follow House of Commons Procedures. This includes using independently run sites like openparliament.ca, as suggested by a Liberal MP (LMP-2). Various groups have been active in attempting to hold the Federal Government accountable regarding GE food policies through websites and grey literature and more formal academic publications, many of which can be found in this research paper's bibliography. Chapters 4, 5 and 6 include a discussion about whether the transparency issues and recommendations raised in these publications have been acknowledged by decision-makers or whether they affected decision-making processes for biotechnology-produced animals.

NGOs also release reports that examine transparency in the Federal Government. Examples of publications include the Canadian Policy Research Network report *Transparency, Trust and Citizen Engagement, What Canadians are saying About Accountability* (2005) and the *Federal Accountability Initiative for Reform* (FAIR), a charity whose aim is to protect whistleblowers, publication *What's Wrong with Canada's Federal Whistleblower Legislation?*

2.3.3. Media

The media play a critical role as two-way channels of communication between the governors and the governed to both reflect and influence public opinions (Kernaghan & Siegal, 1995, p. 503). Members of the media can serve as watchdogs of the public interest and as an important voice for whistleblowers. Members of the media can gain entry into different places and can become the conduits for information. They are in a position to conduct interviews and to write articles that appeal to a variety of audiences through a number of forums (magazines, TV shows, newspapers, exposés, and academic journals), publicize documents obtained through Access to Information requests, and conduct and discuss polls. For example, between 2010 and 2012 reporter Sarah Schmidt wrote articles concerning regulations for biotechnology-produced animals based on documents she obtained through ATI requests.

2.4. Conclusion

Decision-makers do have the capacity to improve transparency and accountability. As examined in this chapter, numerous institutional bodies could theoretically improve both transparency and accountability with respect to biotechnology-produced animals and the food system. The next two chapters explore institutionally-related issues related to transparency by reviewing the history of Federal Government decision-making with respect to foods produced through biotechnology.

Chapter 3: Barriers to Transparency: A History of Decision-Making with Respect to Foods Derived through Modern Biotechnology

3.1. Introduction

The following review of the academic literature respecting Federal Government transparency reveals numerous limitations that constrain effective policy-making with respect to the human consumption of biotechnology-produced animals. These limitations include regulatory inadequacy with respect to as well as parliamentary ineffectiveness in dealing with these animals. This chapter explores the history of policy and regulation with respect to genetically engineered food as well as various limiting factors present within, and external to the government, that constrains transparency of the governing regime.

3.2. Guiding Policies and Principles Respecting the Human Consumption of Genetically Engineered Foods

3.2.1. Departments, Agencies and Core Principles (1980s – 1998)³

Canadian Federal departments and agencies have not been created to deal specifically with products of biotechnology. In the mid-1980s, regulatory authority over products derived through rDNA techniques (modern biotechnology) was given to Federal Government departments that held authority over the same products made from traditional techniques (Moore 2000, p. 96). The three central regulatory departments were Agriculture, Environment, and Health and Welfare. By 1987, these departments agreed on several working principles that included building on existing legislation and internationally developed guidelines, regulating the product as opposed to the process, and using risk-assessment principles (Kneen, 1999 p. 135).

These working principles, including the use of existing laws and regulatory departments to avoid duplication, endured when Canada created a Federal Regulatory Framework (1993) to ensure that “the benefits of biotechnology products and processes are realized in a way that protects health, safety, and the environment” (Health Canada, 2012d).

³See Appendix A for timeline of events discussed in this chapter

They also remained in place when Canada's first National Biotechnology Strategy (1983) was replaced by the Canadian Biotechnology Strategy in 1998. The 1998 Strategy placed an emphasis on strengthening interdepartmental coordination as well as public awareness and participation (Moore, 2000, p. 117). Through the Strategy the Canadian Biotechnology Advisory Committee (CBAC) was created to "provide expert advice to the Federal Government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology" (Health Canada, 2006d). The impartiality of the CBAC was considered suspect as the CBAC resided in the Office of the Canadian Biotechnology Secretariat within Industry Canada, a department that promotes biotechnology (Council of Canadians, 2002).

3.2.2. The CFIA's Role of Regulating and Promoting the Biotech Industry

Consolidation of regulatory functions resulted in the establishment of the Canadian Food Inspection Agency (CFIA) in 1997. The CFIA, which operates under Agriculture and Agri-Food Canada (AAFC), was given the roles of both promoter and regulator of biotech products. Some CFIA initiatives have been questioned for being pro-biotechnology. For example, the CFIA funded information inserts that appeared in the October and November 1999 issues of *Canadian Living* magazine that critics claimed promoted biotechnology (see Appendix A). The connection to the CFIA was not identified in the communication. Another example also perceived to be biased, included a CFIA pamphlet "Food Safety and You" mailed to Canadian households in March 2000 at an alleged cost to taxpayers of \$2.53 million (Kneen, 2000).

3.2.3. Genetically Engineered Food Policy Consultations

Public consultations regarding the formation of Federal biotech policies included workshops in 1993 and 1994 which served as the basis for Canada's regulations for GE foods (Moore, 2000 p. 157). Brewster Kneen outlined multiple occasions where his involvement in the 1993 and 1994 consultations had been used by "industry flacks" to legitimize the consultative process:

There has been nothing democratic about the process of developing public policy for biotechnology...I was there only because I insisted on being present as one of the very few members of the public who had any idea of what was going on in Ottawa... I did this on my own time, and at my own expense. (Kneen, 2000)

Kneen also stated “that there was nothing public or democratic about the so-called consultative process of forming biotech policy and that there never was a consensus on the emerging policy” (Kneen, 2000).

3.3. *The Evolution of GE Food Regulations and Guidelines*

3.3.1. *The Environmental Assessment of Genetically Engineered Foods (2001-2006)*

Up until 2001, new substances found in products regulated under the *Food and Drugs Act* were exempt from the requirements of the *Canadian Environmental Protection Act, 1999 (CEPA 1999)*. In September 2001, those substances became subject to the notification and assessment requirements under the *New Substance Notification Regulations (NSNR)* of CEPA 1999. As discussed in the previous chapters, the NSNR were not developed for substances regulated under the *Food and Drugs Act* (Health Canada, 2010b). An agreement signed between Environment Canada and Health Canada gave Health Canada the responsibility to conduct the full assessment of these substances.

In September 2001, Health Canada’s Environmental Impact Initiative (EII) began formulating Environmental Assessment Regulations (EARs) for new substances in products regulated under the *Food and Drugs Act* (Health Canada, 2010b). Between 2001 and 2006 the EII held multiple consultations regarding the creation of the EARs (listed in Appendix B). Why consultations and publications regarding the EARs stopped in 2006 and what work has happened regarding the EARs since 2006 is unclear. It is also unclear in the literature when work on the EARs will be completed and how appropriate it is to assess the human consumption of biotechnology-produced animals through the NSNR.

3.3.2. *Health Canada’s Safety Assessment of Novel Foods*

When genetically engineered (GE) foods first came into the market in the early 1990s, developers were responsible for the voluntary safety assessment of their GE food product(s). In 1994 Health Canada released the *Guidelines for the Safety Assessment of Novel Foods – Volume I*, and *Volume II: Genetically Modified Microorganisms and Plants* to assist developers in their product assessments.

Health Canada's guidelines referred to GE food as novel foods, and GE plants as Plants with Novel Traits (PNTs) (Food Directorate Health Protection Branch, 1994). In 1995, Health Canada proposed the establishment of a new division in the *Food and Drug Regulation* "that will define the concept of a novel food and provide for notification prior to the sale or advertising the sale of such food products" (Health Canada, 1995, p. 2987). The *Novel Food Regulations* appeared in Canadian Gazette II in October 1999 and made a pre-market safety assessment mandatory for the sale of all foods that had met Health Canada's definition for novel food. Health Canada's definition for novel foods found in these regulations extends beyond products that have been derived through modern biotechnology.⁴

If any new risks appear in novel food products approved through the safety assessment it is up to the manufacturer to make Health Canada aware of the changes. The identification of new risks is limited by the willingness of manufacturers to test their products and to share results with the Federal Government.

As of December 2012, the *Guidelines for the Safety Assessment of Novel Foods* (Volumes I and II) had last been updated in 2006 and stated that the section for Novel Foods Derived from Animals is "Under Development" (Health Canada, Food Directorate Health Products and Food Branch, 2006). According to Health Canada's website "safety assessment criteria for novel foods derived from animals are under development" (Health Canada, 2006d). It is unclear when the guidelines will be updated and what work has been completed on them since 2006. It is also unclear what information Health Canada would need to assess the safety of food products derived through biotechnology-produced animals and what risks the department will be looking at during the assessment process. This is a cause for concern for in 2009 the University of Guelph submitted a notification to Health Canada to approve its EnviropigTM for human consumption (Mann, 2011). As of December 2012, there was no publicly-available information about whether or not Health Canada has reached a decision on the notification.

Critiques surrounding the safety assessment of novel foods have focused on (1) Health Canada's scientific assessment of risks including the use of substantial equivalence and (2) the ability for the regulatory process to take into account new risks introduced by evolving technologies. Health Canada uses the concept of substantial equivalence as a guide in the safety

⁴ The definition of novel foods is included in Division 28, Part B of the *Food and Drug Regulations*. The Regulations can be found on the Department of Justice Canada website

assessment of novel foods (Health Canada, 2006d). The concept of substantial equivalence narrows the safety risks to those already found in the food system. The Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001) "rejected the use of substantial equivalence as a decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities" (Royal Society of Canada, 2001, p. 204, 206). At time of writing, no information is available about how concept will be used in Health Canada's safety assessment of the Enviropig™.

Health Canada's testing of food products derived from biotechnology includes a scientific assessment of risks that, among other things, look at allergenicity and toxicity (Health Canada, 2005). In January 2000 GE Alert, a group of scientists and academics, released a report that revealed testing of the toxicity and allergenicity of GE crops by Health Canada had not been conducted on 70% of the 42 GE crops the department had approved (McKenzie, 2002, p. 170). Dr E. Ann Clark, a Professor at the University of Guelph and member of GE Alert said that the analysis "supports the need for a fundamental reassessment of the process by which the safety of GE food is tested in Canada" (Council of Canadians, 2000).

Health Canada's scientific assessment is also focused on product, not process based risks. In June 2009 a biotech maize named Smartstax™ with eight different gene coding for several pest resistant and herbicide tolerant traits was approved by the CFIA for release in Canada. The Smartstax™ corn is the first GM crop that has more than three GM traits 'stacked' together. As each of the eight GM traits had been individually approved in earlier crops by Health Canada the maize was not classified as a novel food. According to an article by the Canadian Biotechnology Action Network, Health Canada had said a safety evaluation was not needed as new risks are not created through the combination of GM traits (CBAN, 2012a).

A recent laboratory study of rats raised question about the safety of GE maize (Seralini, et al., 2012). Studies of this kind also raise questions about Health Canada's chosen approach. The French group of Gilles-Eric Seralini conducted a peer-reviewed study in 2012 that described harmful effects on rats fed on diets containing GE maize (Seralini, et al., 2012). This study was the first biotechnology-produced animal feeding trial that had been conducted over the lifetime of laboratory rats (two years) to test Monsanto's GM corn NK603 and its herbicide Roundup, approved in Canada in 2001. This length of time far surpasses the one required by Health

Canada. The study found tumors, multiple organ damage and premature death that happened after the typical 90-day period often employed by such laboratory experiments.

Health Canada published a three-page summary of its approval on the GE maize in a 2001 Decision Document based on information provided by Monsanto without its own testing (Health Canada, 2001; CBAN, 2012d). The Seralini study is the first of its kind. Its findings lead one to question both Health Canada's assessment period and requirements of scientific data from companies regarding the length of studies.

3.3.3. Labeling Genetically Engineered Foods in Canada

In Canada, companies are not required to label the process a food product went through, including the use of modern biotechnology techniques (i.e. genetic engineering). As more genetically engineered foods entered the market the Government of Canada recognized that “for many Canadians, labeling of foods derived from biotechnology is an important issue of consumer preference or choice” (Health Canada, 2005b). In September 1999, the Canadian General Standards Board (CGSB) and the Canadian Council of Grocery Distributors (CCGD) established a multi-stakeholder committee to develop a voluntary labeling standard for foods derived from biotechnology.

Some Canadian advocacy groups believe that given that labeling is based on a voluntary labeling standard, the Canadian Government was putting business and trade interests above consumer welfare. Canadian NGOs released multiple documents obtained through the Access to Information Act that showed controversial ties between the departments responsible for the labeling standard project and proponents of the biotechnology industry.⁵ Objections were raised by both public and private actors over the extent of influence that proponents of the biotechnology industry had over the decision to make the labeling standard's project voluntary (Wasylycia-Leis, 2001). A number of NGOs also believed that recommendations outlined by the Royal Society of Canada Expert Panel on the Future of Food Biotechnology were not acknowledged in Federal Government publications, including the CGSB Committee's Consultation Document *Regulation of Genetically Modified Food* (2001).

⁵ Thousands of documents had been obtained through the ATI Act by Bradford Duplisea, a member of the Canadian Health Coalition. (B. Duplisea, Personal communications. October 21, 2011).

Private Member's Bill (C-287) for a Mandatory Labeling Standard for GE Foods (2001)

On February 27th 2001, the same month in which the Royal Society of Canada's Expert Panel on the Future of Biotechnology's Report was released, Charles Caccia, Liberal MP for Davenport Ontario, introduced private members Bill C-287 to amend the *Food and Drugs Act* and make a mandatory labeling standard for GE foods. The amendment also sought to have the Government carry out studies on the long-term effects of GE foods on human health. On October 17th, 2001 when Liberal MPs showed up to the House of Commons to vote on Bill C-287 they found a pamphlet entitled, "vote against bill C-287 and support Canada's Agri-food business" on each of their desks (Freeman, 2001). Bill C-287 was defeated 129 to 91, indicating a divided House of Commons.

MP Policy Briefing "Government's Biotech Strategy Supports Biotech Corporations" (2001)

Subsequently, in May 2001 Judy Wasylycia-Leis, NDP MP for Winnipeg North Centre and a member of the Health Committee introduced Bill C-310 into the House of Commons favouring mandatory labeling. It never reached a vote. Wasylycia-Leis also wrote a policy briefing entitled *Government's Biotech Strategy Supports Biotech Corporations* that appeared in *The Hills*' September 24th, 2001 issue. She wrote that public opposition "from the very heart of Canada's agriculture sector is huge." She referred to an open letter to the Prime Minister "calling for a moratorium on the development of GE wheat." The letter had come from a "broad coalition of more than 200 consumer, environmental, and farm producer groups." Wasylycia-Leis observed that the appeal and the Royal Society of Canada's Expert Panel Report on the Future of Food Biotechnology "provide a picture of what a functional regulatory system could look like and a dramatic sense of what is now lacking" (Wasylycia-Leis, 2001). She asserted that these were two "very public blow[s] to the Government pro-corporate biotechnology policy" (Wasylycia-Leis, 2001).

After reviewing the Royal Society's recommendations, Wasylycia-Leis said that it was apparent why environmental, health and consumer groups had boycotted the CBAC as being too closely tied to industry. For example, in April 2001, sixty-one civil society groups sent letters to the Prime Minister's Office boycotting CBAC and describing it as being fundamentally flawed (Glover, Keeley, Newell, & McGee, 2003). As well, more than fifty NGOs boycotted an invitation to participate in CBAC's consultation as they believed it would legitimize CBAC's

mandate and process, which they believed to be a poor substitute for a more democratic process such as Parliamentary debates and hearings (Council of Canadians, 2002). Wasylycia-Leis felt that reports from the CBAC and CGSB had not recommended changes

to answer the public's doubts and concerns over the testing, monitoring or even identification of GE ingredients... The Federal Government has consistently supported the corporate desire for as little regulation as possible, with little public discussion as possible, maximum secretiveness, minimal labeling and millions of dollars in direct and indirect funding. (Wasylycia-Leis, 2001)

The Standing Committee on Health undertakes public hearings on the Labeling of GE Food (2002, 2003)

The Standing Committee on Health adopted a proposal to study the issue of GE food labeling on October 23rd, 2001, six days after Bill C-287 was defeated. The proposal was suggested through a letter sent to the Committee on October 12 by the Ministers of Industry, Health, and Agriculture. Between January and April 2002, the Standing Committee on Health held four public hearings. Almost twenty groups, representing the various components of the agriculture and Agri-food industry as well as members of NGOs and MPs, made use of these hearings to raise concerns over the conflicting role of the CFIA and funding that had been used to promote biotechnology (See Appendix A). Debate during the hearings occurred over the government's support of the biotechnology industry, cost of a labeling standard and the potential effects on trade (Wilson, 2002; Greenpeace, 2002; Stewart 2002a). The Committee's study entitled *Labeling of genetically modified foods and its impact on farmers* was completed in June 2002.

The Committee's study resumed in March 2003 with participation from Health Canada. In May 2003 the Standing Committee on Health agreed not to pursue its study further after hearing an update from the chair of the CGSB that they were developing a voluntary labeling standard (Health Canada, 2006b).

Labeling and Canadian Biotechnology Advisory Council's Final Report (2002)

On August 26th, 2002, the CBAC released its report entitled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*. The report recommended the development of a voluntary standard for the labeling of genetically modified foods for reasons other than health and safety. The report acknowledged the polarized views about the issue of GE

foods. CIELAP Executive Director Anne Mitchell, one of the twenty- committee members, noted “a majority of respondents to our Interim Report urged a mandatory system” (CBAC, 2002, p. xi). Stakeholders criticized the CBAC’s final report as being biased towards biotechnology (Council of Canadians, 2002). The report recommended that the voluntary labeling standard be reviewed five years after its implementation for adequacy and effectiveness in providing consumer choice, at which time other options including mandatory labeling could be considered (CBAC, 2002). The CBAC’s mandate ended in May 2007 with the release of the Government of Canada's Science and Technology Strategy under the auspices of Industry Canada.

Enactment of the Voluntary labeling standard and Review of the Voting Committee (2004)

The National Standard of Canada’s *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* was adopted by the Government of Canada in April 2004. Some actors saw both the voluntary nature of the Voluntary Labeling Standard Project as well as the CGSB voting committee for the standard as being biased towards the biotechnology industry. Since 2004, interest in having a dialogue over the labeling of GE foods has continued. For example the topic has been formally raised in Private Member’s Bill C-517 in 2008 to require the mandatory labeling of GE food and in *Petition No. 305: Accountability for Labeling of Genetically Modified Organisms* in 2010. In October 2011 the first reading occurred for NDP MP Atamanenko’s Private Member’s Bill C-257 to amend the *Food and Drugs Act* for the mandatory labeling of genetically modified foods (Bill C-257, 2011). The issue also continues to be discussed through the media as answers to labeling GE foods are being decided at the national level and in the international community. As of December 2012, the Government has not released a review of Canada’s voluntary labeling standard.

3.3.4. Federal Government Policy Approach to Food Biotechnology

At the time of writing, 2001 was the last comprehensive Canadian government commissioned report on the biotechnology regulatory framework. This 2001 Royal Society of Canada’s Expert Panel on the Future of Food Biotechnology report was entitled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*. It outlined 58

recommendations that, among other things, included ways to increase transparency and develop regulations for the human consumption of biotechnology-produced animals and the use of biotechnology in animal production systems (Royal Society of Canada, 2001, p. 87-107). The report also called for discussions that went beyond the mandate of the Expert Panel (Royal Society of Canada, 2001). The Government responded with an Action Plan and a series of progress reports.

The last chapter of the Royal Society report entitled “Issues in the science-based regulation of biotechnology” discussed conflicts of interest in the regulatory framework, confidentiality versus transparency in Canadian regulatory science, the validation of science, the increasing commercialization of university scientific research in biotechnology, and the labeling of GM Foods (Royal Society of Canada, 2001). All of these issues involve transparency. The panel noted that there was no way to determine the extent that information requirements were met during the approval process and that there was an inability to evaluate the scientific rigor of the assessment process:

The Panel concludes that the lack of transparency in the current approval process, leading as it does to an inability to evaluate the scientific rigor of the assessment process, seriously compromises the confidence that society can place in the current regulatory framework used to assess potential risks to human, animal and environmental safety posed by GMOs. (Royal Society of Canada, 2001, p. 215)

The report proposed the establishment of a “super regulator” agency with responsibility for the wider issues surrounding genetic modification (Leiss & Tyshenko, 2003, p. 337). It further recommended “Canadian regulatory agencies and officials exercise great care to maintain an objective and neutral stance with respect to the public debate about the risks and benefits of biotechnology in their public statements and interpretations of the regulatory process” (Royal Society of Canada, 2001, p. xi). It suggested “Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and the scientific rationales upon which their regulatory decisions are based” (Royal Society of Canada, 2001, p. xi). It called for clear evidence of the absence of risks and recommended that GE crops and foods should be more rigorously tested and independently reviewed. In February 2001 Dr. Brian Ellis (then Associate Director of University of British Columbia's Biotechnology Laboratory, joint head of the Royal Society of Canada Scientific Panel on Food Biotechnology, and Co-Chair of the Expert Report)

stated the “issue is not with methodology itself but the secrecy that surrounds it” (McDonald, 2001).

The Government response to the Royal Society’s findings was published in the form of an Action Plan in November 2001. The Action Plan recognized the need to continually enhance the regulatory processes and protocols, and the scientific knowledge that support them (Health Canada, 2006a). Subsequent Progress Reports were released in January 2002, May 2002, December 2002, June 2003, December 2003, August 2004, February 2005, and June 2005. A technical discussion report was also released in April 2002. The reports outlined ways to increase transparency and provided timelines.

The Government’s Action Plans and Progress Reports identified strategies and timelines surrounding the creation of regulations for biotechnology-produced animals. The last Action Plan, released in 2005, included a section on genetically modified animals and on tasks that had yet to be completed regarding the regulation of food products from these animals. It also included a timeline for release of updates and said that Health Canada would draft a paper on the assessment for biotechnology-produced animals (Government of Canada, 2005b p. 9, 11, 12).

Little progress appears to have been made. As of October 2012, the researcher has been unable to discover any activities of the Federal Government regarding the Royal Society of Canada’s report after 2005. Dr. Peter Andrée, Carleton University, concluded that, “while some efforts have indeed been made, the Government of Canada continues to fall far short of meeting the RSC Panel’s expectations in key areas, including food safety, environmental assessment, peer review, transparency, and monitoring and surveillance” (Andrée, 2006, p. 1). Why the Government stopped producing reports is unknown, especially since there was no indication in the 2005 report that it was going to be the final report.

Government response to the Royal Society of Canada’s Expert Panel Report resulted in a number of initiatives by NGOs, media outlets and members of academia. Concerns were raised that the Royal Society recommendations were being ignored in the Federal Government’s Action Plans and that when transparency initiatives were undertaken they did not acknowledge the key issues raised by the Royal Society (Andrée and Sharratt, 2004; Wasylycia-Leis, 2001).

In October 2004, Dr. Peter Andrée and Lucy Sharratt, CBAN’s coordinator, released a 53-page report that tracked what the Government had and had not done to implement the RSC Panel’s recommendations and stressed the fact that there had not been a public debate (Andrée

and Sharratt, 2004). With regard to the assessment of biotechnology-produced animals the authors noted the emphasis on science-based concerns and raised concern that “there is virtually no participation by civil society organizations representing the public interest in the process of developing regulations” (Andrée and Sharratt, 2004, p. 20). The authors also noted that the CFIA’s Animal Biotechnology Focus Group Meeting in March 2004 was presented as an effort to “streamline” the regulatory approach to animal biotechnology, which they thought inappropriate as no regulatory approach existed.

3.3.5. Biotechnology in the Spotlight: Private Member’s Bill C-474 (2009) to amend the Seed Act.

The House of Commons continues to debate the selling of genetically engineered foods. In 2009, MP Alex Atamanenko, then MP for BC Southern Interior and the NDP Agriculture Critic, introduced Private Member’s Bill C-474. The bill proposed to “amend the Seed regulations to require an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted” (Bill C-474, 2009). The bill was “a response to the fact that the introduction of certain genetically engineered (GE) organisms can put Canada’s export markets at risk but that current regulation does not consider this question of potential negative economic impacts” (CBAN, n.d.1). In April 2010, a majority of MPs voted in favour of the Bill. On December 1st, 2010, the New Democratic Party used an obscure rule to secure an extended debate in the House of Commons of up to five hours on Bill C-474 for early in 2011. As stated by CBAN’s coordinator Lucy Sharratt: “In our 15-year history with GE crops, a five-hour debate in the House of Commons on the issue is unprecedented...Even if the Bill is not passed, the debate and the public pressure around it has been a huge victory for democracy” (Sharratt, 2011).

A study on biotechnology, to be completed by the Standing Committee on Agriculture and Agri-food, was suggested in September 2010 by Conservative MP, Randy Hoback, a member of the Standing Committee on Agriculture and Agri-Food during a Committee meeting. Hoback suggested the standing committee travel across Canada to visit Universities “where this technology is primarily being undertaken” and then recommend “legislative, policy, and regulatory changes in order to foster an innovative and fertile biotechnology industry in Canada; and that we report our findings as a committee to the House of Commons” (Canada. Standing Common on Agriculture and Agri-Food, 2010). The CBAN believed that the study “is clearly

not designed to ask farmers for their views but will instead provide the industry a public relations platform” (Sharratt, 2011). Lucy Sharratt, the coordinator of CBAN, observed “public pressure to support the Bill has been so strong, however, that, while escaping more hearings on the Bill, the Liberals and Conservatives took action so they could tell constituents they were still examining the controversial issue” (Sharratt, 2011).

The House of Commons Agriculture Committee held 10 public hearings on Bill C-474 between December 2010 and March 2011. The committee members

hoped to gather information on the various stakeholders in the sector, the opportunities biotechnology creates for the Canadian agriculture and Agri-food industry, and problems stakeholders encounter in developing biotechnologies. The Committee also hoped to determine what public policy is needed for the sector to be productive, competitive and innovative and to benefit the Canadian agriculture and Agri-food sector. (Standing Committee on Agriculture and Agri-Food, 2012, p. 45)

The need for greater transparency was one of the themes addressed during the hearings (see Appendix A).

While many Agriculture Committee members were on the road for the study, Bill C-474 was debated and voted on in the House of Commons in February 2011 (CBAN, 2012b). The bill, defeated in its third reading, had gone farther in the Parliamentary process than any previous piece of legislation on GE. Interest in biotechnology continued with the introduction of a Motion for a Moratorium on GE Alfalfa by Liberal Agriculture Critic Wayne Easter in March 2011. The Committee’s study ended with the May 2011 election of the 41st Parliament. A full report was not completed but a summary of the results was included in the Standing Committee on Agriculture and Agri-Food report *Growing Forward 2* (2012). Appendix A of the report includes the Agriculture Committee hearings on the biotechnology industry (Standing Committee on Agriculture and Agri-Food, 2012). The New Democratic Party attached a dissenting opinion to *Growing Forward 2* that outlined recommendations, including the creation of an independent body to peer-review relevant scientific data, and to introduce transparency in the scientific reviews and approval processes (discussed further in Appendix A). Regarding the Committee Hearings the NPD Dissenting Opinion outlined how numerous times the “gaps and oversights in Canada’s regulations governing this technology were pointed out which are seen to have not kept up with the growth of the industry” (Standing Committee on Agriculture and Agri-Food, 2012, p. 80). The Dissenting Opinion was as follows:

It is no small matter that under the current science based approach to our regulations, which relies on privately owned science and a secretive decision-making process, there is no mechanism to allow for consideration of market rejection, or even a special category dealing with genetically engineered animals. (Standing Committee on Agriculture and Agri-Food, 2012, p. 80).

This situation raises concerns about the regulation of biotechnology-produced animals if they are to be produced in Canada.

3.3.6. Health Canada's Interim Policy on Foods from Cloned Animals (2004 – present)

Health Canada's Food Directorate has had an *Interim Policy on Foods from Cloned Animals* in place since 2004. Cloned animals are produced through modern biotechnology and any food products from these animals would be classified as "novel foods" under Division 28, Part B, of the *Food and Drug Regulations*. Developers of cloned animals are requested to "withhold novel food notifications until requirements are determined and further guidance is available" (Health Canada, 2003). In the meantime, Health Canada is obligated to review any submitted application. Information is not publicly available about whether the Canadian government has ever received an application to approve a cloned animal for human consumption and such applications are considered confidential. However, cloned animals have been approved for human consumption in the United States. Canada does not appear to have a method in place to track or to monitor whether food products derived from cloned animals have entered Canada's food supply. An example of these concerns can be illustrated by examining current regulatory processes regarding biotechnology-produced fish.

3.3.7 Limitations of Regulatory Approval Processes Regarding Biotechnology-produced Fish

Inadequate transparency and accountability mechanisms regarding biotechnology-produced fish regulations could result in the unintentional introduction of biotechnology-produced fish into the food supply through an egg hatchery or research facility. Limitations also result from the public's inability to know or affect what decisions are being made about the production of biotechnology-produced fish.

The Commercial Production of Genetically Engineered Fish Eggs

In September 2010, the United States Food and Drug Administration held public hearings regarding an environmental assessment application that AquaBounty Technologies Inc. had submitted regarding its AquaAdvantage® salmon. Documents released by the Food and Drug Administration revealed the company's plan to produce the eggs in Prince Edward Island and have them shipped to Panama for grow-out. The final product would then be sold in the United States (Patterson, 2011).

The company currently has a research facility in P.E.I. The application process to request approval to commercially produce GE salmon eggs falls under the *Canadian Environmental Protection Act* (Patterson, 2010). Whether Environment Canada is looking at an application is confidential. In November 2010 the P.E.I. Coalition for a GMO Free Province, an NGO, sent a letter to P.E.I. Premier Robert Ghiz stating

[N]either the Government of P.E.I. nor residents will be notified by Environment Canada if AquaBounty requests approval for production of GE salmon eggs on the Island... Environment Canada will assess the environmental risks of producing the GE salmon eggs in 120 days in a completely secret process...There is no public input, and no notification to the province or public disclosure. This process is flawed. (Broderick, Labchuk & Boyd, 2010)

The group asked the Premier “in the interest of fairness, transparency, and fisheries conservation” to, among other things:

insist Environment Canada notify Prince Edward Island when AquaBounty requests approval for commercial production of GE Atlantic salmon eggs, that the province be consulted on environmental risk questions and be notified immediately if approval is granted (or refused). (Broderick, Labchuk & Boyd, 2010)

As of December 2012, no information is available about whether the company has submitted any requests or whether requests are under review.

In January 2011 a coalition of opponents to AquaBounty Technologies Inc's plans met with P.E.I.'s Premier and P.E.I.'s Provincial Environment Minister to address “growing opposition to AquaBounty's development of GMO salmon in P.E.I.” (CBC News, 2011). The coalition asked for public consultations on AquaBounty's export plan. Premier Ghiz agreed to pursue more transparency around AquaBounty's export plans. Leo Broderick of the Council of Canadians noted the following:

We did get a commitment from the Premier that he would play a more active, positive role in trying to get Environment Canada to be more transparent... And so, he is going to write Environment Canada asking whether or not AquaBounty has requested approval for commercial production of GMO Atlantic salmon, salmon eggs on P.E.I. And he's going to ask that the P.E.I. government be part of the environmental risk study. That's very good. (CBC News, 2011)

Broderick said the Premier agreed to take the group's demands for a consultation process to the Liberal Caucus. As yet, there is not written information available about what has since transpired.

Limitations to the Regulatory Process Regarding the Production of GE Fish

Internal records obtained under Access to Information legislation reveal that Environment Canada acknowledged it “isn’t sure it can fully protect wild fish stocks if it approves the commercialization of the hatchery for genetically engineered salmon eggs” (Schmidt 2011b). In consideration of a hatchery application from AquaBounty, Environment Canada “has to determine whether to concern itself only with the production and transportation of GE fish eggs from P.E.I.” or “whether the Federal Government also has a duty to consider wider potential effects GE fish could have on this country or the global environment if the fish ever escaped the Panamanian facilities and migrated into Canadian or international waters” (Schmidt 2011b).

According to the internal records

Environment Canada concluded that the narrower oversight option - while ‘easily enforceable by inspecting shipments at the port of export’ in Canada – ‘falls short’ of meeting Canada's legal obligations under CEPA ‘because it does not fully consider potential effects within Canada’. (Schmidt 2011b)

As there is a “broad legislative requirement under CEPA to assess potential risks to the global environment,” Environment Canada recommended that the scope of the environmental risk assessment take a “fulsome approach... for the full protection of the Canadian environment, in particular Canadian fish stocks” (Schmidt, 2011b). According to Schmidt this could be “beyond the capability of Canadian authorities” (Schmidt, 2011b).

Internal records also obtained through the ATI Act revealed that two senior scientists specializing in biotechnology and aquaculture from the Department of Fisheries and Oceans (DFO) are concerned about “limits and possible constraints of the current Canadian regulations for GE fish” (Schmidt, 2011c). DFO officials voiced concern in 2010 during consultations with

AquaBounty officials and scientists from the DFO, Environment Canada, and Health Canada (Schmidt, 2011c). According to minutes released under the ATI Act

DFO clarified that while the risk assessment will focus on potential effects in Canada, there is potential risk of fish migrating back to affect Canadian fish stocks... DFO requested that containment and limitations to which companies in other countries will have to comply be clearly outlined in the notification. (Schmidt, 2011c)

Two government experts raised issues through email correspondence regarding the meetings draft minutes about Canada's regulatory approvals process to approve GE fish. The experts cited are Caroline Mimeault, a scientific adviser at DFO's Biotechnology and Aquatic Animal Health Science, and Robert Devlin, a DFO scientist who studies risk assessment of GE fish at the department's Centre for Aquaculture and Environmental Research in West Vancouver (Schmidt, 2011c). Devlin co-authored a journal article "that found dispersal behaviour has been affected by introducing an outside gene into a fish, so GE fish may venture into habitat previously not used by wild fish" (Schmidt, 2011c).

Mimeault wrote that the Government "may be constrained" by regulations concerning information that can be requested by a company wanting to commercialize GE fish (Schmidt, 2011c). According to Schmidt's article, Lucy Sharratt from CBAN "is worried inadequate regulations could hamper the ability of DFO scientists to carry out a comprehensive risk assessment of a GE fish application... This could be a case of good scientists inside departments constrained by regulations" (Schmidt, 2011c).

With limited public information about the safety assessments of biotechnology-produced animals, any information that the regulatory departments do provide to the public takes on extra importance. Internal DFO media notices prepared in May 2009 in the event of journalists' questions about AquaBounty, stated that Canadian regulations "currently provide an effective regulatory framework for protecting the environment from potential risks of GE fish" (Schmidt, 2011c). A draft of the media notice prepared by the CFIA in August of 2010, stated: "The GE salmon are bred in contained, land-based systems and are reproductively sterile females, eliminating the threat of interbreeding amongst them or with native populations" (Schmidt, 2011c). DFO scientist Mimeault reviewed the media lines and stated

I would rather use a less definitive term such as 'significantly reducing,' as opposed to 'eliminating,' as we know that the possibility for accident release can never be completely

eliminated and that the technology to render the fish reproductively sterile is not 100 per cent efficient. (Schmidt, 2011c)

CBAN's coordinator Sharratt said "the documents confirm the fish cannot be contained, infertility cannot be 100 per cent achieved, and when fish escape, there's a risk it will come back to affect our fish stocks" (Schmidt, 2011c).

Public Responses to the Commercial Production of Biotechnology-produced Fish

Many interested stakeholders have attempted to be involved in, or influence, the decision-making process. Ruth Salmon, Executive Director of the Canadian Aquaculture Industry Alliance (CAIA) said that "the Canadian aquaculture industry does not support the commercial production of transgenic fish for human consumption" (Sharratt 2010b).

In March 2011, Fin Donnelly, NDP MP and Fisheries and Oceans Critic, tabled a motion in the House of Commons "asking for transparency and more study before genetically modified (GM) Atlantic salmon are approved for human consumption" (CBAN, 2011a). The DFO's ability to regulate was in question as well as whether the regulations in place may be inadequate to protect the food supply. Chapter 4 further explores the issues that were raised and what happened with Donnelly's motion.

3.4. Additional Limitations to Transparency outside the Regulatory Process

Limits to transparency outside of the scope of GE food regulations can also hamper the public's ability to hold government accountable in this policy area. These include the limited authority of Health Canada and the CFIA's Notice of Submission Project; a lack of long-term testing and traceability initiatives; and the potential to allow for accidental contamination of the food supply.

3.4.1. The Voluntary Notice of Submission Project (2004)

It is not mandatory for regulatory departments to release information concerning notifications they have received from companies concerning novel foods (CFIA, 2009a). The CFIA and Health Canada launched a project in 2004,

to post on the CFIA website 'notices of submission' that describe the product and the data they receive from certain product developers who have requested safety assessments

of plants with novel traits (PNTs) for unconfined release and safety assessments of novel feeds and novel foods derived from PNTs. (CFIA, 2009a)

The Voluntary Notice of Submission Project applies to companies that are part of Croplife Canada, an industry association that represents approximately 85% of plant biotechnology developers in Canada. Comments can be made to the CFIA and Health Canada on the content of the notices of submissions. How comments are taken into consideration is unknown. There is nothing in place for posting notices of submissions from product developers who have submitted notifications concerning novel foods derived from biotechnology-produced animals.

3.4.2. A Lack of Long-Term Testing

Health Canada does not appear to conduct long-term tests on food products derived from biotechnology. According to Health Canada, “there is no current evidence to indicate that long-term studies are needed to ensure the safety of foods produced using this technology” (Health Canada, 2006d). Health Canada’s website states

Should developments in the technology result in modifications that provide significantly different nutrient combinations or other novel food characteristics not previously encountered in the food supply, such foods may require additional considerations to address long term health effects. In such cases long term studies may be a valid approach to include in the assessment of the overall safety of such products. At this time no products representing such true novelty to the food supply have been proposed for commercialization. (Health Canada, 2006d)

As the above paragraph indicates, there appears to no publicly-available information about proposed government directions of future policies respecting studies on the introduction of novel foods

3.4.3. A Lack of Traceability Initiatives

The Government also does not appear to have traceability initiatives specifically set up to monitor biotechnology-produced animals. Biotechnology-produced research animals that were not approved for human consumption have ended up in the food system. In 2002, the University of Guelph sent eleven Enviropig™ piglets to a rendering plant where they were unintentionally turned into animal feed (Strass, 2002). Egg farmers, turkey farmers, and broiler chicken

producers in Ontario were sold 675 tons of contaminated poultry feed. As then Vice President of Research at the University of Guelph Alan Wildeman said “Things you don’t expect to happen can happen” (Strauss, 2002). At that time scientists did not have to tell the Federal Government about their work if the scientists did not think their research projects would endanger the environment (Strauss, 2002). The incident led the Ministry of the Environment to review the procedures for allowing bioengineering research (Strauss, 2002). Two years later, in 2004, experimental GM pharma-pigs from the Quebec company TGN Biotech were accidentally turned into chicken feed instead of being incinerated (Sharratt, 2010a).

The Auditor General’s Office’s 2008 report questioned the ability of regulatory bodies to effectively regulate biotechnology-produced fish used for and stated:

Departmental officials have incomplete knowledge of research and development activities because proponents are not required to disclose that they are conducting research and; there is no mandatory reporting of an accidental release of a research and development organism into the environment. Although such a breach is subject to Environment Canada’s compliance and enforcement policy, the Department could only act on it once it became aware of the breach. The result of these weaknesses is that the extent of research under way in Canada and any accidental release of GE fish may not be fully known. (Commissioner of the Environment and Sustainable Development, 2008 p. 4)

As of December 2012, it still appears to be the case that it is up to a company to inform the Federal Government of activities going on in research facilities and any incidences, including animals escaping from research facilities and/or the accidental introduction of the animals into the food supply.

Traceability Initiatives surrounding Animals approved for reproduction and exportation

For the first time in Canada, a GE Animal, the Enviropig™ was approved for reproduction and exportation in February 2010 under *New Substance Notification Regulations (Organisms)*. This was also the first time that Environment Canada was directly involved in the approval of a genetically engineered organism. Environment Canada was given the responsibility for assessing the environmental risks of the Enviropig™ because Canada does not have specific regulations for biotechnology-produced animals (CBAN& Beyond Factory Farms, 2010).

In *The Risk Assessment Summary Conducted Pursuant to the New Substances Notification Regulations (Organisms)* for the Enviropig™ “a significant new activity (SNAc)

provision was recommended based on the uncertainties regarding possible environmental impacts of the notified organism in activities outside the scope of this assessment” (Environment Canada, 2012). Publicly available information is unavailable with respect to whether or not traceability measures will be made specifically for biotechnology-produced animals.

In sum, it appears that the current regulatory and policy framework does not have labeling, specific traceability, or human health studies to discover potential problems that could occur post-market (Standing Committee on Agriculture and Agri-Food, 2012, p. 81). This lack of clarity is also the case with respect to traceability measures, including long-term testing or the mandatory labeling of food products derived from biotechnology-produced animals.

3.4.4. The Issue of Accidental Contamination

In 2009, the European market closed its doors to Canadian flax because flax exports from Canada contain GE flax (CBAN, 2012b). Approved by the CFIA and Health Canada for environmental release (1996) and human consumption (1998), the “CDC Triffid” GM flax was deregistered in 2001 by the CFIA, making it illegal to sell the seeds (CBAN, 2012b) (see Appendix A). The flax was never commercially grown in Canada and all existing stocks of Triffid were supposed to have been destroyed following deregistration (CBAN, 2012b). As of December 2012 the European market remains closed to Canadian flax.

Government regulations may be heading in a more lenient direction about accidental or unintentional contamination of genetically modified organisms into the food supply. In 2011, the Federal Government held consultations on Low Level Presence, “the unintended presence, at low levels, of a genetically modified (GM) crop that is authorized for commercial use or sale in one or more countries, but is not yet authorized in an importing country” (AAFC, n.d. p. 3). The Federal Government has stated it will hold more public consultations (Schmidt, 2012). It is unknown whether this would also apply to biotechnology-produced animals.

3.4.5. Summary

Canadian citizens are not informed when a notification to request a safety assessment for novel foods is made to regulatory bodies. A biotechnology-produced animal can be approved for reproduction and exportation without being approved for human consumption. In a few cases,

the current traceability measures have resulted in the unintentional introduction of research animals into the food supply.

3.5. Polls and Surveys: Canadians' Acceptance of Biotechnology-produced Foods and Animals

A key element of this discussion is the degree to which Canadians themselves are concerned about a) GE foods and its regulation and b) whether it is important to have more transparency with respect to government decision-making processes in this area. Various polls have been held to determine consumer acceptance of food produced through modern biotechnology and modern biotechnology in general. A variety of polls conducted between 1994 and 2008 by media outlets, Industry Canada (1994) and NGOs all concluded that the majority of citizens polled wanted labeling of GE foods and were hesitant about GE foods (Found in Appendix C: Polls). On the other hand a 2008 survey by the biotech industry group BIOTECCanada, said that 79 percent of Canadians agreed that “biotechnology” would bring benefits to agriculture (Martin and Grey, 2010, p.13).

More recently, in February 2010, Agriculture Canada commissioned a telephone survey “after Government officials hosted a series of meetings with AquaBounty Technologies Inc., as part of pre-notification consultations with the company concerning the human consumption of the animals” (Schmidt, 2011a). The survey compared its results to one that had been commissioned earlier (See Table 3.1).

Table 3. 1. Comparison of Survey Results from 2006 to 2010: Canadian’s Opinions on Biotechnology-produced animals

February 2010- 2006: Percentages of Canadians who agreed they:	2010	2006
Do not approve of GM fish, except under very special circumstances	37%	24%
Do not approve of GM animals under any circumstance	29%	21%
Are not at all confident in Ottawa’s ability to regulate GM animals	27%	23%
Are not at all confident in the government’s ability to regulate GM fish	23%	16%
Are extremely or very confident in Ottawa’s regulatory	14%	19%.
Approve of GM fish as long as the usual level of government oversight and control is in place	13%	24%
Are extremely or very confident in Ottawa’s regulatory oversight of GM animals	11%	18%
Approve of GM animals as long as the usual government oversight in place	9%,	14%

Source: Schmidt (2011a)

The survey “cites ‘some erosion’ in confidence in the Federal Government’s safety and regulatory systems for biotechnology and a widening ‘regulatory gap’ in dealing with new technologies for the growing skepticism” (Schmidt, 2011a).

Notable actions regarding the Enviropig™ have been undertaken by the National Farmers Union and CBAN. The National Farmers Union of Ontario in 2010 passed a Resolution that they “oppose the commercial production of the Enviropig™ in Canada and request that Ontario Pork and OMAFRA [Ontario Ministry of Agriculture, Food and Rural Affairs] withdraw support for the Enviropig™ and the University of Guelph shut down the project immediately” (NFU Ontario, 2010, p.1). In May 2010 CBAN launched a Stop the Enviropig™ campaign that included a petition, letters to be sent to MPs, articles, policy briefings, debates, and speaking tours. Lucy Sharratt from the CBAN said that “Enviropig™ was allowed to happen because there has never been a democratic debate in Canada about genetic engineering and there is no public overview of the direction of public research” (Sharratt, 2010a). Increasing transparency and accountability in the regulatory processes could strengthen public confidence in the Federal Government’s regulatory processes. This subject will be explored further in Chapters 4 and 5.

3.6. Conclusion

This chapter identified limitations to transparency and accountability in Federal policy-making with respect to the human consumption of biotechnology-produced animals. The historical analysis in this chapter revealed an enduring lack of transparency and accountability regarding the Federal Government's decision-making processes and institutions for GE foods which has continued to the present day. This allows for the identification of barriers to transparency that exist within the decision-making structure for GE animals. The chapter outlined specific limitations to regulatory processes for biotechnology-produced fish. The chapter also showed issues regarding GE crops and food are still being discussed (Chapter 3.6). Also, polls and surveys have shown support for biotechnology-produced animals is low. Recommendations to increasing transparency and accountability regarding GE foods have also not been taken into account.

The available literature shed little light about how the science-based approach and principles will apply for the safety assessment and environmental assessment of foods derived from biotechnology-produced animals. Regulations for these animals have not been finalized. The Enviropig™ notification for human consumption was still being assessed by Health Canada at the time of writing. Issues regarding the evolution of the science based regulatory approach have been raised on multiple occasions such as the appropriateness of using the principle of substantial equivalency in risk assessments and the reliance on Confidential Business Information during the assessment processes for novel foods. Specific concerns relate to the lack of timelines for completion of regulations, the ability of regulatory departments to regulate biotechnology-produced animals, the lack of public consultations, and the fact that Royal Society of Canada's recommendations have been ignored. Government Action Plan initiatives in response to the Royal Society of Canada's Expert Panel Report on the Future of Food Biotechnology also were not fully acted upon.

The chapter also highlighted the constraints on the ability of the regulatory system to take into account identified concerns. Moreover, GE food regulations do not take into consideration any social, ethical or economic impacts including determining the impact of approving a novel food to export markets. This chapter sets the stage for Chapter 4's discussion of the issue of transparency and human consumption of biotechnology-produced animals based on extensive interviews with key stakeholders.

Chapter 4: Primary Research Findings

This chapter describes the project's primary research findings. It provides a description of the field research undertaken and the major themes identified in the interviews. Field research was undertaken to answer questions that could not be found through the literature review. It was also undertaken to identify what key stakeholders believe to be barriers or opportunities to transparency concerning the human consumption of biotechnology-produced animals. An open ended research approach was useful as the amount of information available regarding biotechnology-produced animals is limited as policies have not been finalized and decisions have not been made. Representative groups were selected based on; their knowledge of what barriers and opportunities have existed in the past that might affect the transparency of federal policy making for biotechnology-produced animals; their knowledge of the Federal Government's policy making process regarding biotechnology-produced animals and; their connection to biotechnology-produced animals. They were selected through a preliminary review of literature, the snowballing method, and personal attendance at relevant events.

Representative groups that the interviewee attempted to contact included:

- Federal government employees in Health Canada, the CFIA, Environment Canada, the Auditor-General's Office; the Department of Fisheries and Oceans; the Food and Drugs Liaison Office.
- Members of advisory bodies including the Standing Joint Committee on the Scrutiny of Regulations and the Environmental Assessment Working Group; the Agri-Subcommittee on Food Safety and; the Food Expert Advisory Committee.
- MPs from various political parties including critics and members of various committees.
- NGOs including consumer groups, citizen's groups, farmer's organizations and environmental and food security organizations.
- Industry representatives including food distribution company and biotechnology groups.
- Members of academia who specialize in biotechnology or public policy.
- Members of the media who have written about the topic of transparency surrounding the Canadian Federal Government's decision-making processes concerning biotechnology-produced animals.

- Representatives from the University of Guelph and AquaBounty Technologies Inc.,

4.1. Description of Field Research

Nineteen adult participants from the representative groups stated above agreed to the use of their interview in the research project. The direct positions and affiliations have been removed to protect anonymity. As shown in Table 4.1. participants represent a variety of stakeholder groups.

Table 4. 1. Stakeholder Groups Represented through Interviews

Group	Participant Profile	Quantity	Code
Members of Parliament	Liberal MPs	2	LMP
	Conservative MP, Member of the Standing Committee on Agriculture and Agri-Foods	1	CMP
	A. Atamanenko, NDP MP	1	NDP – A
	J. Wasylycia-Leis, Former NDP MP and Health Critic	1	NDP - J
	MP from the Opposition	1	OPP - 1
	MP from the Opposition	1	OPP-2
Green Party PEI	Leader, Sharon Labchuk	1	GPPEI
Green Party	Member	1	GP-1
Federal Public Servant	Environment Canada Employee	1	PS-1
	Federal Government official who works in the area of food and health policy	1	PS-2
Environmental and food security NGOs	Lucy Sharratt, Canadian Biotechnology Action Network (CBAN) Coordinator	1	NGO - 1
	Council of Canadians representative	1	NGO - 2
	National Farmers Union (NFU) representative	1	NGO – 3
	CIELAP Executive Director (1992 – 2009) who represented Quakers on the CBAC	1	NGO - C
Academia	former molecular geneticist who is now a sociology professor at the university of Québec in Montreal who researches the sociopolitical implications of the life industries and who is a specialist in the study of Canada's environmental risk assessment of GMO	1	ACAD-1
	Rod MacRae, Food Policy Consultant, York University Associate Professor	1	ACAD - 2

Media / Journalist	Consumers affairs reporter from Postmedia News	1	JOUR
Industry	Spokesman from a large Canadian food distributing company	1	IND

Participants consisted of members of political parties including eight elected officials who have discussed and voted on the topic in Parliamentary proceedings and one member of the Green Party’s shadow cabinet; one public servant involved in regulating and updating regulations concerning biotechnology-produced animals; one Federal Government official who works in the area of food and health policy; representatives of environmental and food security non-governmental organizations who actively research the topic and/or have raised concern over the transparency of regulations and policies surrounding the human consumption of biotechnology-produced animals; two members of academia who have studied or are studying the issue of GE foods in Canada; a consumer’s affairs reporter from a major news outlet who has obtained Access to Information documents and written about biotechnology-produced animals and; a spokesman from a large Canadian food distributing company. Several participants had experience in multiple roles related to the research topic. Participants’ diverse backgrounds offered a variety of perspectives with respect to biotechnology-produced animals and associated policy-making processes.

Phone interviews took place November and December 2011 and March through August 2012. The researcher selected questions from a pre-approved list of open-ended questions (see Appendix D) to help direct the interviews. Each participant signed a consent form giving permission to the inclusion of identifying information and the use of quotations (either direct or anonymous) (See Appendix E for the consent form).

4.2. Findings / Major Themes

Following up on questions raised in the literature review, open-ended interviews and grounded theory were used by the researcher to identify what participants thought were the most relevant barriers and opportunities concerning the transparency and accountability of Federal decision-making processes and institutions with respect to biotechnology-produced animals. Interview transcripts were analyzed to find commonalities that formed into themes. Findings were organized in this method so that barriers to transparency emerged through the interviews, rather

than the interviewer directing the participants to pre-conceived barriers. This data was organized into seven thematic areas.

A majority of participants discussed the lack of publically available information. Most participants pointed out inadequacies in the current policy and regulatory framework. Most interviewees also suggested that there is a lack of political will to ensure transparency. Just over half of interviewees hypothesized that this could be due to the Federal Government’s biased agenda towards biotechnology and that transparency appeared to be a growing problem due to declining avenues for public participation and reduced consultative initiatives. A few participants stated transparency appeared to be a growing problem due to a disempowered Parliament and a dramatic decline in public servant interactions and communications flow. Table 4.1. lists what participants commented on what themes. The remainder of the chapter examines each theme.

Table 4. 2. Major Themes identified by Research Participants

N=19

Theme	Topic	No. of Participants
1	Lack of Publicly-Available Information	18
2	Inadequacy of the Current Policy and Regulatory Framework	16
3	Lack of Political Will to Ensure Transparency	15
4	Declining Avenues for Public Participation/ Consultative Initiatives	11
5	Bias of the Government's Agenda towards Biotechnology	11
6	Disempowered Parliament	8
7	Decline in Civil Servant - Public Interaction and Communications Flow	4

4.2.1. Lack of Publicly-Available Information

The lack of publically-available information concerning federal decision-making processes and institutions was mentioned by a majority of participants. This was particularly the case with respect to the inability for consumers to identify GE food products that are on the market. Concerns were also raised by many participants over the confidential nature of the application processes. The Federal Government and biotechnology industry’s release of information was also raised by many participants. A few participants noted a lack of public information being released through the media in general as well as a lack of public awareness and understanding

regarding biotechnology-produced animals. A few participants noted the lack of publicly-available information concerning the Federal Government's assessment of scientific risks. A few participants also mentioned the Federal Government's focus on scientific risks. Some participants pointed out difficulties related to obtaining information through the court system and Access to Information requests. Also noted was a public inability to gather information on research facilities that contain biotechnology-produced animals. A few participants highlighted the difficulty in understanding the ambiguous language used by the Federal Government regarding genetically engineered food and biotechnology.

Identifying GE Food Products in the Market

Participants identified the inability of consumers to identify GE products in the Canadian marketplace as a limitation to transparency. A Green party shadow cabinet member maintained that consumers should have the ability to choose (GP-1). A Federal Government official who works in the area of food and health said that mandatory is the least favourite of the regulatory tools and is very difficult to reverse.⁶ The official said that consumers could avoid GE foods by buying foods with Canada's organic labeling standard (PS-2). The former executive director of CIELAP and member of CBAC said that without a mandatory labeling standard for GE food consumers have to have the knowledge, money, and time to make informed choices (NGO-C). A former molecular geneticist and current sociology professor who is a specialist in the study of Canada's environmental risk assessment of GMO cautioned that the biotechnology industry keeps trying to corrupt the organic standard to include GMOs as it's "the last frontier for them" (ACAD-1).

An Opposition MP believed that the pro-business Government is currently allowing the biotechnology industry to prevent mandatory labeling (OPP-1). Alex Atamanenko, An NDP MP and member of the Standing Committee on Agriculture and Agri-Food, said that the huge biotech lobby is the reason that there is no labeling (NDP-A). Another MP from the opposition who had actively followed these issues confirmed labeling did not appear to have received much attention in Ottawa in recent years (OPP-2). A few participants also pointed out that there had

⁶ Information on *Canada's Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* can be found through (Canadian General Standards Board, 2004) Information on the Government of Canada's position on identifying GE food products in the market can be found through (Health Canada, 2006b).

been no assessment of the labeling standard itself and that the CBAC had been shut down before it could assess the voluntary labeling standard (NGO-C; NGO-1). A former molecular geneticist who is a specialist in the study of Canada's environmental risk assessment of GMO said that people are focused on the labeling issue as it is something tangible that consumers can rally around because there is no transparency in the regulatory system and no transparency in the marketplace (ACAD-1).

The Confidential Nature of Applications

The majority of participants noted the confidential nature of the application process for the environmental release and/or human consumption of biotechnology-produced animals. They mentioned both the assessment of science-based risks, the confidential nature of the application itself, the lack of a review process or public debate, and the risk of contamination of the food supply. A journalist found it odd that the Government can't say if they're reviewing an application and that citizens can't be engaged when regulators are reviewing applications (JOUR).

A representative from the Council of Canadians, an NGO, said that there is no involvement in the environmental assessment processes for biotechnology-produced animals by the public, the provincial governments, and local experts. The representative mentioned the lack of public input, provincial consultations or notification that would be required during the application process to convert AquaBounty's research facility into a commercial egg hatchery (NGO-2). The Canadian Biotechnology Action Network (CBAN) coordinator noted that Environment Canada would have to gain permission from AquaBounty before discussing any applications concerning the AquAdvantage™ salmon (NGO-1). A member of the opposition maintained that the provincial government of P.E.I. should be able to ask and respond to questions regarding what is going on within the province (OPP-1).

A Conservative MP asserted that the regulatory process is transparent and pointed out that decision documents related to Health Canada and the CFIA's safety assessments are posted on the department websites once a product is approved for market (CMP). The MP said that releasing information on all of the applications would be an overload of information and believed some people would see it as being a smoke screen in which maybe hidden certain controversial applications. The MP pointed out that the regulatory process can take more than ten years and

not all products make it through the application process and/or never reach the market. The MP believed that the step which determines if the product is safe for humans and/or animal feed is the most important step in the eyes of the public (CMP).

The Federal Government's Release of Information

Many research participants identified a lack of federally-released information as a serious problem. A reporter talked about the difficulty in gathering information from government officials and experts, because the Government's communications protocol discourages interviews in favour of written responses drafted through media relations departments and approved by political staff (JOUR). Along the same lines, one professor who is a specialist in the study of Canada's environmental risk assessment of GMO described information that is released as too little, too late and usually after the product has been approved. The academic said that there is no real way of gathering information unless you know what is going on in the laboratories (ACAD-1). CBAN's coordinator said that the burden was placed on the public sector to ask, seek and beg for information (NGO-1). Sharon Labchuk, former leader of the Green Party of P.E.I. and a member of the NGO Earth Action P.E.I., said that while government has a responsibility to provide information, the reality is that it rarely does and when it does, the information cannot be trusted as it will have come from industry. It's become the job of NGOs to ferret out whatever alternative information is available and try to disseminate it (GPPEI). Representatives of NGOs maintained that they did not have the capacity or resources that are required to remain informed (NGO-C; NGO-2). A former Executive Director of the Canadian Institute for Environmental Law and Policy (CIELAP) said that biotech products are coming out "so fast and furious, nobody has the resources or time to pick them off one at a time" (NGO-C). The CIELAP representative added that transparency was not possible if information that is released by the Federal Government is one-sided. When the Federal Government was developing its BioPortal website (BioPortal.gc.ca) the developers were asked, "Where are you going to put the other side? Where are going to put some critical information about what the concerns are or what the risks might be?" The CIELAP representative said that even though some of the bureaucrats were quite concerned their political masters were not (NGO-C). Other participants agreed that the information being released by the Federal Government was one-sided. A Green Party member maintained that any information coming from the Government is one sided, is not

evidence-based and repeats the same information from the biotechnology industry as though it is true (GP-1).

The Biotechnology Industry's Release of Information

A few participants identified the minimal amount of information released by the biotechnology industry because it owns all of the information as a limitation to transparency. A representative of the Council of Canadians stated the lack of transparency from the companies who patent GE products is one of the problems with the lack of research on the health and the environmental impacts of GE products. The representative also pointed out that that in the past independent bodies were able to and did conduct similar research (NGO-2). An MP from the opposition said that the biotechnology industry is sensitive about speaking. The MP added:

I support biotechnology. I am one of those that believe it's going to ultimately help. I say to the industry many times 'it's your secrecy that has raised suspicions' ...they come into my office, I say to them you have to demystify and de-cloak and they say 'yes you're right' but I'm not sure that much of an effort is made. (OPP-2)

The MP maintained that if the biotech industry made the effort "people will become a little more accepting in what it is the industry is trying to achieve and what they're doing" (OPP-2).

Information Released through the Media

A few participants also pointed to a lack of information released through the media and the general lack of public awareness and understanding regarding biotechnology-produced animals. A reporter who has been following the issue stated she wished media attention was higher as the industry is moving along in developing and marketing biotechnology-produced animals as food (JOUR). A former member of CBAC and CIELAP said "we are speaking to ourselves" and questioned how to connect with consumers (NGO-C). An NDP MP identified the difficulty in explaining a complicated situation such as food regulation in a way that the majority of people can understand and relate to. The MP said that it is an especially slow process to educate consumers when the focus is science. The MP added that often the media has not done an excellent job in presenting the case clearly (OPP-1). A NGO representative stated that "you'd think fairly educated people who actually access progressive media would be understanding this, but they're not" (NGO-3).

The Federal Government's Assessment of Scientific Risks

A few participants identified the assessment of scientific data in the risk assessment processes for the human consumption and environmental release of biotechnology-produced animals as an area of concern. Other identified issues related to transparency with respect to the lack of a third-party review of submitted data. A representative from the Council of Canadians said that the data submitted by companies is not replicated by Health Canada or Environment Canada (NGO-2). A Green Party Shadow Cabinet member observed “if the studies are held in confidence there is no accountability. If science is not peer-reviewed or published in a journal it is not science” (GP-1).

One professor who is a specialist in the study of Canada's environmental risk assessment of GMO noted that the public doesn't have much of a chance of holding the Government accountable because they don't have access to any kind of information about how products are being regulated (ACAD-1). The professor described information the Government publishes on its website as very uninformative, noting “in terms of the scientific data and the data that is being used to approve these [GE] crops I think even the scientific community has very little to say about these issues because no one has access to documents or to the studies” (ACAD-1).

A food policy consultant said that when they did get access to data packages for GE crops that had been approved under the regulatory framework, the packages “had so many flawed assumptions and completely inappropriate data sets, when you look at them you wonder what kind of moron would approve this” (ACAD-2).

When speaking about these kinds of challenges, CBAN's coordinator noted that regulatory departments are restricted in how transparent they can be due to the use of confidential business information in the assessment process to approve biotechnology-produced animals for human consumption or environmental release (NGO-1).

The Federal Government's Publication of Risk Assessment Reports (regarding Scientific Risks)

An Environment Canada employee noted that the department had taken its own initiative, partially in response to be consistent with the Cartagena Protocol on Biosafety, but also because the department understands the merit of being more transparent, and was posting some risk assessment reports/decisions online (PS-1). Due to business information being confidential, the applicant needs to approve what information is included in the published report before the

decision can be posted on Environment Canada's website. The employee stated it could take one to three years after a regulatory decision was made before the risk assessment report is posted (PS-1).

The Federal Government's Focus on Scientific Risks

A few participants criticized the regulatory framework for limiting risk assessment to science-based risks and not taking into consideration socio-economic, economic or ecological risks. A food policy consultant and the former leader of the Green Party of PEI both said that the regulatory system was not designed to manage the issues concerning novel technologies that go beyond science (ACAD-2; GPPEI). A Federal Government official who works in the area of food and health policy said that the use of science-based risks during the application process and the separation of politics and science in safety regulations was appropriate. The participant said that once Health Canada assesses a product as safe "let the market decide" (PS-2).

One professor who is a specialist in the study of Canada's environmental risk assessment of GMO believes that in terms of biotechnology-produced animals there are other issues including ethical issues, animal welfare, animal rights that are slightly different than with GE crops. This former geneticist also said that ethical issues related to animal engineering affect people in a different way than with GE crops. The former geneticist also noted "you're dealing with a different level of genetic modification with much more complex genomes and more unpredictable consequences." The specialist noted how New Zealand had stopped research on GE Sheep as they were so mutated (ACAD-1).

Obtaining Information through the Court System and Access To Information (ATI) Requests

A few participants raised the issues of expense and time as impediments to their ability to obtain information on biotechnology-produced animals through official channels such as the court system and Access to Information (ATI) requests. CBAN's coordinator described ATI requests as a barrier to information, a hurdle you have to cross (NGO-1). A member of the Green party mentioned the expense involved in going to court to obtain information:

The general public does not have the money to do the studies, the Green Party don't have the money to go to court to force them to release their studies and we don't have lobby money to force our politicians to actually present both sides of the story. (GP-1)

A representative from the Council of Canadians said that the expense of an ATI request as the reason for not having submitted a request on the AquAdvantage® salmon (NGO-2). A reporter, in recognition that the only route to find information is through the ATI Act, expressed disappointment that interested parties had to use this cumbersome and time-consuming route to get information about projects such as the AquAdvantage™ salmon. The reporter also said that if the government is not providing information, using the ATI Act can work “like a fishing expedition”. The reporter also described ATI requests as “time delayed accountability”, referring to an experience in November 2011 when she received a response to an ATI request she had submitted in 2009 (JOUR). A Liberal MP referred to frustration with ATI requests in terms of the need to be both very specific in order to get the information you want and unconcerned about the cost (LMP-2).

CBAN’s coordinator said that an ATI request doesn’t result in full disclosure (NGO-1). One professor who is a specialist in the study of Canada's environmental risk assessment of GMO didn’t mind the seeing blacked out information on ATI requests and said that in her experience there was enough information that wasn’t blacked out to see how regulatory approvals are conducted (ACAD-1). However she did describe an experience she had in the 1990s a few weeks after getting an ATI package regarding GE crops:

We got a letter from a well-known transnational agrichemical corporation saying if you ever release this information we will sue you, it was a really threatening letter...When we published our results we were very careful about what we could say – I don’t think we gave up on giving out the information but we just had to be very careful about how we used documents. We were joking that maybe someone made a mistake that someone sent us information by accident... Someone in the government must have said to them we have released this information to these two people and next thing you know Monsanto has my home address, it was pretty scary. At the time we were hearing about how Monsanto was going around with security guards taking samples from farmer’s fields to see if they had violated patents. (ACAD-1)

The Risk of Biotechnology-produced animals not approved for Human Consumption Contaminating the Food Supply

Concerns were raised by a few participants about the inability to assess the risk of biotechnology-produced animals unintentionally entering into Canada’s food supply. The former leader of the Green Party of PEI Labchuk and a representative from the Council of Canadians

both raised concern over the confidentiality surrounding research facilities including AquaBounty Technologies facilities in P.E.I. The NGO representative said that there was a huge potential for eggs to escape from AquaBounty's research facility (NGO-2). Another NGO representative and an NDP MP both raised concern over the possibility of biotechnology-produced animals escaping and breeding with their conventional counterparts (NGO-3; NDP-A). Labchuk stated "we have no idea what's going on there" and questioned who would know if AquaBounty had an accident (GPPEI).

The Federal Government's Use of Ambiguous Language

One participant highlighted difficulty in understanding the ambiguous language used by the Federal Government regarding genetically engineered food and biotechnology even for Members of Parliament who were attuned to such issues (OPP-2). A member of the Green Party's shadow cabinet also found that the Standing Committee on Agriculture and Agri-Food's *Growing Forward 2* (2012) used key words like innovation that could mean anything (GP-1). An NDP MP pointed out that language is critical and is used to present a case of making people more assured that things are fine. The MP mentioned the ambiguity of terms such as novel food (OPP-1). A Conservative MP said that biotechnology is a very broad umbrella issue that covers many different areas. The MP stated one of the challenges they had in the Standing Committee on Agriculture and Agri-Foods was that witnesses presenting to the Committee often narrowed their biotechnology discussions on genetically modified organisms (CMP).

4.2.2. Inadequacy of the Current Policy and Regulatory Framework

Sixteen participants said that the Federal Government's lack of political will to ensure transparency has led to inadequacies in the current policy and regulatory framework. A few participants brought up limitations caused by a market-driven regulatory system; limitations to updating regulations within the existing policy framework and; the unbalanced approach of the regulatory process between the right to know and the interest of the proponent. A few participants noted the absence of GE food regulations. A few participants noted inadequacies are heightened by the fact that the Government's slow pace of change is relative to the faster pace of technology.

A Market Driven Regulatory System

Seven participants believed that the biotechnology industry is driving the Government's agenda. A former NDP MP stated "We've just seen a complete move towards an absolute abandonment of the precautionary principle and the do-no-harm principle and a complete shift towards a market-driven market-regulated system" (NDP-J). The former MP said that the latest cutbacks to food inspections have left industry determining their own safety and the Federal Government without the adequate staff to do proactive investigations. She said "the industry has gotten stronger, the present Government ever being the puppets of big industry and not doing anything to cross large corporations" (NDP-J).

A Green party shadow cabinet member stated the need for independent scientific studies to be done because industry was in control of Health Canada "in the application process and the industry themselves are supplying the science" (GP-1). The member said the issue is one of transparency and accountability and not capacity (GP-1). One professor who is a specialist in the study of Canada's environmental risk assessment of GMO said

The argument is that Agriculture Canada is there to promote biotech products because they have invested so much of public funds into the research and the development of that industry that it is in their interest to make the regulatory system as minimalistic as possible and to have the least constraints on corporations. (ACAD-1)

The Unbalanced Approach of the Regulatory Process

Several participants (seven) identified a lack of balance in the regulatory process between the right to know and the interest of the proponent. A spokesman from a large Canadian food distributing company brought up the Government's obligation to protect the commercial interest of the proponent (IND). A representative from the Council of Canadians said that the regulatory approach gave companies preferential treatment at the expense of openness (NGO-2). A participant stated that her fall-back position in the CBAC was that scientific discussions are not enough without considering ethical, social and equity issues and that in any case citizens have a right to know – even if the scientists consider there is no reason for concern (NGO-C).

A spokesman from a large Canadian food distributing company said that it wasn't a question of challenging the safety of food products; there were potential consequences, intentional and unintentional, to everyone in the supply chain and to consumers. The spokesman said that this was especially true with a new commodity in the absence of a unique traceability

and labeling system. The spokesman remained confident in the regulatory approval process. He added that a company's existence was determined by the degree of consumer confidence in a product suggesting that if the Government opened its doors to broad consultations and the consideration of non-scientific facts, markets could be shut down by poorly informed consumers (IND). To address this problem, he said the process has to strike a balance between the interest of the proponent and encouraging innovation and providing transparency and making information available to the public. He referred to what happened to Canadian flax (which was banned in Europe as discussed in chapter 3) as an example of what can happen when a regulatory approval system protects the interest of the proponent, but offers no transparency or opportunity for other interested parties to comment. He questioned whether that same course of events would transpire as novel animal products are brought forward (IND).

With regard to releasing information on applications a Conservative MP pointed out why that would be a problem from the perspective of a business, stating that

From the competitor point of view – wouldn't every business like to know that? If you were a car dealer, wouldn't you love to know about Honda's next model? Honda doesn't want you to know until it comes to market – especially given its investment into it.
(CMP)

The spokesman from a large Canadian food distributing company said that it goes beyond the question of whether domestic consumers are confident and are being consulted because unapproved trans-border crossing, intentional and unintentional, is very important for the industry (IND). An NGO representative pointed out that the Enviropig™ was thought to be slated to be an export product to China and asked, "If it is something that we don't want Canadians to eat or Canadians don't want to eat, then why should we impose it upon our brothers and sisters in other countries" (NGO-3)?

Limitations to Updating Regulations

A few participants discussed limitations to the process of updating regulations. CBAN's coordinator and an Environment Canada employee both said that regulators are boxed in by policy and restricted in the changes they could make and how transparent they could be. CBAN's coordinator said that any regulations designed to address whether biotechnology-produced animals are safe to eat would have to be made within the existing policy framework for novel

foods. The coordinator said that the actual focus for change under the existing policy or existing regulations was narrow and that ethical and economic questions were considered to be irrelevant (NGO-1). A representative from the Council of Canadians said that after meeting with Health Canada “[Health Canada] does think that there should be some major changes but they can’t do that, it has to come through Parliament” (NGO-2).

One professor who is a specialist in the study of Canada's environmental risk assessment of GMO does not express much confidence in the process:

[T]he feeling is we’re just kind of making it up as we go along and we’re not really focusing on who is really being hurt by this and who is being affected by what is going on in terms of policy development or industrial development. It’s scary for a lot of people because we don’t know where it is going (ACAD-1).

An Environment Canada employee said that because legislation often defines the role of departments (what they can do under an Act and what they cannot) and since the Act dictates what is in the regulations, including amendments to the regulations, changing the way something is regulated requires a change in the Act that governs that process. So, in order to critique regulatory issues around foods that have been produced through modern biotechnology effectively, one would have to critique the overall policy direction that led to that regulation. Therefore, changes to the overall policy would be needed (arising from the population at large to effect a political change) to create the change in the legislation which, in turn, could change the approach in regulation (PS-1). A former member of both CBAC and CIELAP said that ten to fifteen years ago the Government was more open to having policy discussions, citing the CBAC as an example. The former member added that the policy changes that are still needed are the policy changes that CIELAP was calling for ten to fifteen years ago (NGO-C).

CBAN’s coordinator said that it was obvious that reforming regulations is not going to address the problem of a lack of democracy around foods produced through biotechnology. She said that the actual perimeters of the scope of the policy have to be expanded and a total policy shift is required in order to reform the regulation of GE food (NGO-1). The coordinator believed that the policy and regulatory framework are very clear and that any of the changes CBAN would like to see would upend the policy and that is why regulatory changes that invite public discussion including small ones like disclosure will not happen. The coordinator stated the

Government is very clear that they don't want discussion and that is why meaningful changes for transparency haven't happened, why nothing has changed in the entire framework of novel foods and why the same barriers exist (NGO-1).

The Absence of Genetically Engineered Food Regulations

Three participants discussed the absence of regulations specific to GE foods and the use of the Novel Food regulations. A Federal Government official who works in the area of food and public health policy said that there are benefits to having a novelty regulation because risks could be introduced through conventional breeding (PS-2).

Although it seems counterintuitive, the official noted that biotech products were the original focus when Division 28 of the *Food and Drugs Act* was set up in the 1990s (as discussed in Chapter 3). At the time, the big driver was biotechnology. The official said that the way Division 28 was written provided the flexibility to capture new technologies and utilize experts in various fields: “you are sure that the person looking at allergenicity knows something about the topic and about food in general” (PS-2). A food policy consultant said:

Civil servants understand themselves to be experts at certain things and that certain things are their terrain and it is not for the public to be engaged in these kind of things...A lot of times that's really what people believe who are working in these organizations and it's not that they're always completely misinformed on this. There are certain things they do have expertise on, but when their decision-making authority is rooted in the process that has never really had a public debate like GE, then it becomes highly problematic. (ACAD-2)

The official said that the first approach had been to use existing regulations and not create a separate biotech regulation in order to capture biotech products within the specific contexts of food and environmental release. The official also said that in the 1990s, after seeing the complexity of the pre-market authorization process, they decided to use the pre-notification process for novel foods was used because using this approach meant they would avoid the very lengthy process of going through Canada Gazette I and II (PS-2).

The official mentioned challenges concerning the breadth of the Novel Food Regulations and how long a food product should be considered novel. The official questioned once there is familiarity with something “is it still novel or run of the mill? Thirty years from now will GM foods be regulated as novel?” The participant said that as scientists gather information through

case-by-case assessment, there is a need to question whether the formal policy of the approach is sufficient, insufficient, or over kill (PS-2).

The spokesman from a large Canadian food distributing company stated many scientists would say some of the techniques of traditional breeding used in plant production are more radical than GE in the sense of modifying the life form. He said that doesn't seem to cause concern and questioned where the line should be drawn, and asked what type of technological innovation is so novel that society should demand traceability, labeling, and consultation (IND).

The spokesman stated that parallel learning can be found between how the Government has or has not proactively set a framework for managing cloned animal and the government's approach to novel foods. The spokesmen criticized both cases for lacking an overall risk assessment or policy framework. The spokesmen stated that Canada's lack of an overall risk assessment or policy framework for cloned meat had resulted in the Government's inability to distinguish, test or trace imported cloned meat. The spokesmen noted Health Canada had asked potential applicants to voluntarily withhold submitting an application until a risk assessment framework was in place. Currently Health Canada has no legal basis to refuse a cloned meat application and would assess these food products under the Novel Food Regulations. Canadians would not know an application was put forth until it was approved (IND). The food company representative pointed out that technology to clone animals had been approved for use in the USA for human consumption which occurred after a lot of policy deliberation and after the industry had agreed on a system of identification and traceability of cloned animals. The spokesmen stated the possibility exists that milk and meat from cloned animals has been imported into Canada and the Federal Government has no process to distinguish it or test whether the imported meat is from a cloned animal. The spokesmen said that the risk of government inactivity could shake confidence and result in economic harm (IND).

The spokesman said that a framework for biotechnology-produced animals should be established and public consultations undertaken before any applicant comes forward in order to provide an understanding about the basis upon which an individual application would be considered. The participant stated this has never happened for cloned animals. The participant said that over five years ago Health Canada stated they were going to do a general risk assessment to decide if a cloned animal should be considered novel or whether unique regulatory process should be in place. The participant stated that although Health Canada representatives

said it had been done and there had been inter-departmental committee talk about it, nothing has come out about it (IND).

The Federal Government's Slow Pace of Change with respect to updating Regulations

Three participants discussed the Federal Government's slow pace of change, worsened by staff cutbacks. With regards to updating the Guidelines, a Federal Government official who works in the area of food and health policy said that the work of regulators is prioritized based on funding, time, and resource issues (PS-2).

An NDP MP elaborated on this point by noting that the Federal Government is a big machine and most of the time change is often incremental and doesn't happen quickly (OPP-1).

Adding to the situation, a reporter observed that biotechnology experts she's interviewed suggest the government seems incapable of properly assessing cutting-edge products, both because of a lack of expertise and outdated regulations (JOUR). An NDP MP said that when the MP asked DFO for a status report they did not provide a lot and said that there wasn't a lot going on. The MP believed them and that it was probably low on the priority list in terms of developing guidelines and regulations (OPP-1).

4.2.3. Lack of Political Will to Ensure Transparency

Related to the previous theme, the majority of participants in the study suggested the reason for a lack of publicly available information is that the Government doesn't have the political will to ensure transparency. Many participants raised an issue as the lack of research being done by both the Federal Government and independent bodies. Moreover, when attempts have been made to hold the Government accountable, it's been an issue of accountability without results and that there is a lack of democratic participation. Participants also said that the Government's food safety initiatives have been superficial. A few participants also discussed the declining access to information from the Federal Government. They said that Federal Government initiatives to increase transparency do not address identified issues of transparency.

A Lack of Government and Independent Research

Ten participants also stated that transparency was difficult to achieve due to the limited amount of research being done by the Government and independent bodies. Former MP Wasylycia-Leis

said that things had become less transparent and that there had been no progress in terms of independent research (NDP-J). NDP MP Atamanenko said that the Government had not done any truly independent studies on the health effects of GE foods “there isn’t really an independent study done before we release GE organisms into the environment... A lot of the research is done by big companies and, upon researching them, you know their agenda” (NDP-A).

A professor who is a specialist in the study of Canada's environmental risk assessment of GMO also stated no one wants to do a study against GE for fear of losing their lab or funding (ACAD-1). A member of the Green Party’s shadow cabinet pointed out that companies can say there is no scientific proof that GMOs have health risk because they can control the studies (GP-1). The member echoed the need for real independent scientific testing:

Companies are donating to the universities and they’re all friends so they can go to the university scientist, and even if he is trying to run an independent study, they can say, you really don’t want to do that study. Just like the MPs it’s all very tightly controlled (GP-1)

Participants also discussed the limitations to the type of research that was being reviewed by the Government. Past MP and Health Critic Wasylycia-Leis said:

During the whole period when I was raising these issues they always tried to suggest to us that research had been done and there was no evidence to suggest GE products were not safe beyond a reasonable doubt, and when you look below the surface, and this was fairly well critiqued by outside scientists, it was clear that they were trying to compare chemical makeup of the product, talk about chemical equivalence. They didn’t get at the root cause of long-term effects of GE food on human health and well-being (NDP-J).

Wasylycia-Leis said that the current and previous Governments had put the onus of scientific health studies onto the industry itself “even though they [the industry] have a vested interest in one outcome” (NDP-J). She said that while the results are kept confidential when people have gone to court to force the studies to be made public, the studies are scientifically bizarre, “they messed with the science in order to try and get a particular outcome” (NDP-J).

Two other participants also mentioned the lack of long-term testing by the Federal Government. A former member of CIELAP said that no data was being collected in the long term (NGO-C). A Green Party member said that there was no money for long-term testing (GP-1).

A Lack of Democratic Participation

A number of participants (nine) stated that when they have held the Government accountable, it's been an issue of accountability without results and that there is a lack of democratic participation. An NGO representative stated

We can hold the government accountable but they don't really care... We make them accountable, we call them to task... they just continue what they're doing... We can hold them accountable using facts and figures and hard data but they'll choose to ignore it (NGO-3)

CBAN's coordinator also commented that the issues go beyond whether the framework is transparent. She said that the Government is transparent about its bad regulatory policy and there is no democratic participation:

the industry talks about transparency a lot. When faced with a series of critiques about GE they say okay we need to be more transparent. It's a fall back agreement on behalf of the industry and Government... more transparency means consumers won't be afraid etc, that's the discourse of the industry side on transparency, just providing enough and although the framework is transparent it's obvious reforming regulations is not enough and a policy shift is necessary. (NGO-1)

She said she doesn't see a window for the public to participate regarding GE food in a democratic way.

There are consultations on reform or development of new regulations which are done with every process. Our fundamental criticism is that the whole framework for regulating GE foods is deliberately non-transparent... The system is expressly designed to exclude public participation, because often the government will agree, yes we do need to increase transparency. That's not the issue that's the symptom of a deeper problem. (NGO-1)

A food company representative also pointed out that the timeframe and broader implications surrounding the Enviropig™ application were not being transparently debated (IND).

Superficial Food Safety Initiatives

According to five participants, food safety transparency initiatives focus on symptoms and not on root causes. A member of the Green Party asserted that food safety initiatives are completely meaningless without traceability in the processing system (GP-1). Regarding food safety initiatives a former MP and Health Critic observed

It's a good camouflage isn't it? It creates the illusion among the public that the food we eat is safe beyond a reasonable doubt when in fact nothing has changed below the surface...They'll create the illusion that makes it hard for anyone to be a naysayer...It's only gotten worse in terms of actual real meaningful research, independent research, and proactive investigations. (NDP-J)

A Conservative MP maintained that the system is working and Canadians have confidence in the system and know that the food they buy is safe (CMP). The MP pointed out that there is a long process with many checks and balances before a product can be introduced into the food chain. The MP said that people will be opposed to the Enviropig™ but it is not on the market (CMP).

The Declining Accessibility to Information from the Federal Government

Four participants noted a declining amount of accessibility to information on the part of the Federal Government concerning biotechnology. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO noticed that the Federal Government had taken down a lot of information about biotech policies, reports, and Canada's biotech strategy from its websites after she had been monitoring them for a long time (ACAD-1). The professor stated “now they make you go through ten steps to get the report.” The professor continued

There's a real toughening up of the release of information by the Harper government in particular. Everybody says it feels that the Conservatives are not even talking to the media half the time – if you need information you can't even talk to someone on the phone, they say send it in writing and you won't get responses. They've really tightened the screw on information –it's not a good day for democracy. Transparency is definitely not at its highest at the moment – not that it's ever been very good but it's getting worse. (ACAD-1)

Federal Government Transparency Initiatives not Addressing Identified Core Issues

Three participants commented that only superficial updates had been made to the regulatory framework and did not address identified issues of transparency. A food policy consultant said the modest increases in transparency are not about challenging the core of the system (ACAD-2). He noted that a lot of department statements were window dressing as the result of department obligations (i.e. a command from Treasury Board) (ACAD-2)

CBAN's coordinator and Past MP and Health Critic Wasylycia-Leis both talked about the Government's unsatisfactory response to the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology recommendations. The coordinator said that the Government

made the mistake of asking an independent body to take a look at the future of biotechnology regulations as the RSC Expert Panel had established major critiques over the transparency of regulations (NGO-1). Wasylycia-Leis described the Federal Government Action Plans as being part of a clever strategy for the Federal Government to “wait it out, knowing that parties will change, that people will lose interest or the media will lose interest” (NDP-J). CBAN’s coordinator said some things in the Action Plans had been reversed or resulted in useless initiatives like the voluntary notice of submission project. She said that the Government had only made changes in response to industry pressure and its trade agenda and that the only change made regarding public pressure, the voluntary notice of submission project, was a hard fought win that resulted from all the questions of transparency. However, she added that it was set up by Croplife, remains voluntary, does not address what the public was asking for, and does not address biotechnology-produced animals (NGO-1). She also noted that there was still no access to how regulatory decisions get made or to the data in decision making behind regulatory approvals (NGO-1).

4.2.4. Declining Avenues for Public Participation and Consultative Initiatives

A majority of participants, including the majority of NGO representatives, said the lack of Federal Government transparency is manifested through reduced opportunities for public participation and consultative initiatives including participating in government consultations and the use of advisory bodies.

Participating in Government Consultations

Seven participants described different experiences with participating in Government consultations. Two NGO representatives said that they had informative and productive meetings with regulators to gain clarity on the process of regulating biotechnology-produced animals. One said they had an informative meeting with Environment Canada where the department went through the process of what they will do once it gets an application from AquaBounty (NGO-2). CBAN’s coordinator Sharratt said they had requested a meeting with regulators to gain clarity on the process of regulating the Enviropig™ and AquAdvantage® salmon. Sharratt said that although the meeting was productive CBAN’s preference would have been to provide advice on policy not regulations (NGO-1).

In contrast, Labchuk, the former leader of the Green Party of PEI and member of the NGO Earth Action P.E.I. felt that the Government representatives she had met with were not knowledgeable on the topic and/or were disinterested. In reference to a meeting with P.E.I. Premier Robert Ghiz Labchuk stated “he’s not really worried about it, he doesn’t really care, he doesn’t think it’s a problem. He told us ‘he is genetically engineered’ and is not going to be chasing down the Government” (GPPEI).⁷ Labchuk added “the Premier’s staff looked very uncomfortable standing around him when he said this” (GPPEI).

A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said she didn't believe that consultations meant that much. She said that for the consultation on the 1998 Strategy:

They were supposedly asking the public what they thought about GE foods even though they'd been eating them unknowingly for years. They came and said ‘okay we’re going to have consultations about the future of GE foods in Canada, so here’s GE food, do you want this scenario or that scenario?’ There was no way in the whole consultation process to say we don’t want GE foods. They had come with two prepared scenarios. Most of the participants were essentially pro-GM so it was fine for them. It was so ridiculous that a bunch of us, Environmental-NGOs, activists, we just walked out. It was not a consultation it was not a debate. Everything was decided ahead of time, there was no democratic process to speak of. We were just there to make them look good because then they could say we consulted with ENGOs and civil society groups etc. (ACAD-1)

The specialist said that attending a consultation

doesn't guarantee that you are going to get any more information or that you're going to know what is actually going on – it is already going on underneath your nose...The problem is the Federal Government is not being an honest broker / partner because they don't have a process for decision making that is inclusive. It's between them and industry, what they call ‘stakeholders’. If you're a random person you aren't a stakeholder unless you're organized some big consumer organization that is threatening to withhold your dollars, they are not going to even look at you. That's the reality of the system. It's really frustrating. You know that you're right and they're wrong. (ACAD-1)

The specialist pointed out that Canada's two biotechnology strategies (discussed in Chapter 3) were developed out of order. Implementation of the regulatory system was addressed before the GE strategy itself. She stated how the first one “was to implement the regulatory system and say we are consulting with Canadian society and stakeholders and we are developing this great regulatory framework – after the fact that it was already set up” (ACAD-1). She asserted that the

⁷A representative from the Council of Canadians and a representative from NFU also attended the meeting (GPPEI)

focus of the second strategy, the National Biotechnology Strategy (1998) was “to have a societal debate around the acceptability of GE foods - and this is four years after GE foods were already in the environment and in the marketplace” (ACAD-1). The specialist noted that you should “first have a social debate about whether you want them and then you make the regulatory system but we did it the other way” (ACAD-1).

A member of the opposition noted that there was public interest in the issue. One MP observed that when more than 300 people attended a forum on biotechnology in Guelph, people were in shock at the high attendance. The MP said that a lot of the people had had extreme misgivings about genetic modification (OPP-2).

The Ability to Participate in Government Consultations

Four participants discussed limitations surrounding their ability to participate in consultations, specifically having to find out if there was one; difficulties with the process, format, and cost for participation; and the limited focus. An NGO representative stated “It’s a highly complex issue so unless you’re following the issue really, really closely and are able to keep up with the language and understand the language and the process, it’s very intimidating” (NGO-3). The NGO representative said you had to know of the consultation and the time frame of the consultation. “You need a full-time staff person almost really to keep up with what’s going on” (NGO-3). As to the language used in online consultations the participant said, “many farmers don’t understand the language. It’s not that they’re stupid it’s just a very academic bureaucratic language and it’s very ambiguous” (NGO-3). The participant pointed out that a lot of consultations are held in Ottawa and that the funding that used to be provided for one or two representatives from each organization to attend the meetings is no longer provided. The participant added that when NFU did attend meetings regarding GE foods the majority of people were from industry and NFU would be marginalized as the nay-sayer. The participant said they attended consultations regarding GE food “at our own cost, our own peril and our own mental health... You really feel that it’s useless it’s very demoralizing. They’ve already decided and it’s getting to be increasingly like that and we basically stopped attending” (NGO-3).

The ability to participate based on the focus of consultations was also raised. One food and health policy official stated that the Health Canada wanted feedback on the guidelines for biotechnology-produced animals but that the feedback had to relate to science (PS-2). CBAN’s

coordinator said that limiting the consultation's focus to science-based risks meant limiting the expert participants invited to those who understood the science behind biotechnology:

There is only a small group of people and organizations that have expertise in GM animals. The industry has a great advantage as they can maintain scientific expertise. Industry is the first place outside of Government that Government will go to to make changes to regulations. (NGO-1)

The Use of Advisory Committees

The limited mandate and term of the Canadian Biotechnology Advisory Committee (CBAC) was identified as an issue affecting transparency by two participants. A former member of the CBAC said there had been a lot of controversy even when the committee was set up over whether it was “just a greenwash”:

There's no means of holding that committee accountable because it's been disbanded. It was replaced by a committee set up under the auspices of Industry Canada, the Science and Technology Advisory Committee... there was no attempt to continue having a conversation with any civil society groups that did not see technology as the economic driver of the 21st century and the job creator. (NGO-C)

One MP observed that a number of people are keenly interested in getting the CBAC back together and stated intentions to press the issue in Ottawa (OPP-2). The MP also said that regulations are needed specifically with respect to the coexistence of GE and non-GE crops and food and for low-level presence and there should be a venue where stakeholders have an opportunity to talk and in some instances self-regulate. He said that he would prefer moving forward with both CBAC and the Science and Technology Advisory Committee (OPP-2).

4.2.5. The Bias of the Government's Agenda towards Biotechnology

A strong theme emerged around the inadequacies of the current policy and regulatory framework. Eleven participants stated that these were the result the Government's agenda that is biased in favour of biotechnology. Participants considered current and previous government's at the Federal and provincial levels. The former leader of the Green Party of PEI said that P.E.I.'s provincial government is the main driver and has been and is aggressively pushing and promoting biotechnology. She pointed out that biotechnology has been mentioned in throne speeches under both the Conservatives and the Liberals (GPPEI).

A NDP MP said the Federal Government has had a pro-industry bias for at least 20 years (OPP-1). A Former NDP MP said that the biotechnology industry has dominated the scene with the Federal Government with both the Liberals and Conservatives parties choosing “to lay down and rollover whenever industry speaks” (NDP-J). An NGO representative said “We’re in a stage with our Government that it doesn’t matter what you say to whom, they’re blinkered. They’re going where they’re going and how we change them apart from getting rid of them, I don’t know” (NGO-C). Another NGO representative stated “I feel sad that the food is such an election issue and even the Liberals sit on their hands because they don’t want to piss off their industry buddies. They could have supported Bill C-474. I know Wayne Easter [Liberal MP in P.E.I.] really well and he refused” (NGO-3). NDP MP Atamanenko said the industry is driving the agenda and the government has bought into the corporate agenda. With respect to his Bill C-474 Atamanenko said:

I was told basically by the Parliamentary Secretary and the Conservatives, the reason they don’t want any of the stuff being debated is because the biotech industry is basically telling them, look we spent all this money on research. You guys start interfering, you start debating the merits of this technology, we’re going to pull out our research. Simple as that. I would call it corporate blackmail. (NDP-A)

A Green Party shadow cabinet member asserted that “they are changing bills and Parliament is doing things and they’re not telling the full story” (GP-1). The participant said that although the Government says it is driving things for a strong economy, she believes those to be meaningless words:

How does this particular product bring me a strong economy? As a farmer and scientist I’ve been involved in politics, I pay attention to what’s being said and try to research it to be able to make sense of it. They are saying GM is going to help the economy and I know for a fact that it does not. The only piece of the economy that GM products are helping is the company’s bottom line. (GP-1)

Past NDP MP and Health Critic Wasylycia-Leis, in reference to the Health Committee’s Standing Committee on Labeling (see chapter 3), commented that sometimes the Government will strategically let something go through that they don’t want knowing full well that it may run out of time, or Parliament will be prorogued, or an election will happen so the work will just die. Wasylycia-Leis had been the Health Critic from 1998 to 2003 and from 2007 to 2012. She said that the Standing Committee on Health “had not been great” for taking up the issue of labeling. “It goes back to why this tight control in this area?” She identified the predominance of industry

and the fact that the Liberals, the Government at that time, did not want to open the issue up as “they were well down the path of having devolved the system and had moved towards industry sponsored research and a risk management model that they had no intention of discussing. They had bought into the agenda” (NDP-J).

A representative from the Council of Canadians concludes:

Zero transparency – all there is is a push to get things on the market and it is being done for the benefit of industry...it’s almost a cookie-cutter approach... Just speed up the process to make it easier for industry to get their product on the market without people like us saying, well wait a minute, let’s unpack this and take a look at the costs and benefits. We would like to be more engaged and we would like it to be easier for us to be engaged. (NGO-3)

A Liberal MP suggested that in the last budget there was an intentional defunding of alternative voices “whether it’s on environmental movement or other issues” (LMP-1). The representative from the Council of Canadian said

It’s not just about the actual issue, about GE wheat or GE pigs. It’s also about transparency. This is another thing they’re doing behind closed doors for the benefit of industry without any respect or concern for the farmer or the consumer or the environment or the long term ramifications of their position (NGO-3).

4.2.6. Disempowered Parliament

The lack of Federal Government transparency is in part manifested through a disempowered Parliament including the limited ability of parliamentary proceedings to discuss and/or influence GE food policies according to eight participants. They brought up limitations to transparency surrounding a reduced oversight in parliamentary regulatory functions. Participants also raised limitations facing MPs, the use of committees, bills and motions, and having discussions ‘in-camera’.

Limitations Faced by Members of Parliament

A few participants discussed limitations surrounding the ability of Members of Parliament (MPs) to shed light on issues of transparency. A Food policy consultant described the GE regulatory environment as:

a deeply buried architecture that runs under the radar in part because the elected officials don’t have expertise to challenge it or the parliamentary procedures. For examples if

you're a parliamentarian and you disagree with the way legislation or a policy initiative is unfolding what are you going to do about it? You don't have an oversight capacity, staff to understand it, or the ability to follow it deep into the bowels of the bureaucratic process. (ACAD-2)

One MP from the opposition said that people have enormous expectations of MPs and that MPs are not listened to and the press time they receive is based on the controversial nature of what they are discussing (OPP-2).

Former NDP MP Wasylycia-Leis and a current NDP MP Atamanenko discussed how their interactions with the biotechnology lobby affected their ability as MPs. Wasylycia-Leis said "I can say for certain when I was raising these issues there was always a lobby of big food production companies and GE producers. I remember Monsanto being so pervasive and dominant in everything that was going on" (NDP-J). Atamanenko similarly observed:

I was at a cocktail party and one of the executives of Croplife said 'look we don't even want your bill debated'. So here we are, a representative of this industry is telling an elected official that he does not have a right to have a full democratic debate on the topic as important as this. That is absolutely reprehensible. (NDP-A)

Atamanenko added that before his bill to amend seed regulations, Bill C-474 (discussed in Chapter 3), was coming to a final vote (February 2011) the biotech industry had organized fifty meetings in December 2010 with Liberal and Conservative MPs to lobby against the bill and that there was a full-page ad in the Hills Times newspaper. With regards to the biotech industry he said "They are powerful. They are calling the shots" (NDP-A). A Liberal MP said that barriers MPs face have led to there being "no way for MPs to empower themselves" (LMP-1).

One participant, a food policy consultant, said that Parliament's traditional function of overseeing Government had been reduced and had given rise to a regulatory apparatus that is lacking in transparency and accountability

Now you have situations where agents of Parliament including the Auditor General or the Environmental Commissioner or the Privacy Commissioner have become effectively the opposition... The rules of Parliament have been so altered that the opposition parties don't have the means or resources or the capacity or the rules to actually provide this oversight function which is supposed to be the main role of Parliament. These obviously are much bigger than the GE regulatory story but those things have happened to allow this kind of construction of a regulatory apparatus to exist. (ACAD-2)

The consultant said that centralization of power in the PCO/PMO has also limited the role of MPs with respect to transparency (ACAD-2).

Participants brought up the limited ability of bills and motions to make any changes. The food policy consultant said bills and motions regarding biotechnology food products “do not have any hope in passing in Parliament because the civil service is going to do everything it can through the Privy Council Office and Prime Minister’s Office as it [bills and motions] completely challenges the fundamental architecture they have deliberately constructed” (ACAD-2). A Liberal MP added that “In general private members bills are tough to get through... once you make them political that just drives the divide down the middle of the house and often if they are criticizing the Government a fair bit, automatically the Government will vote against it (LMP-2)”.

Limitations to the use of Parliamentary Committees

A few participants raised the issue of how and whether biotechnology-produced animals are discussed in committees. An NDP MP brought up difficulties experienced by standing committees regarding capacity, the competitiveness to getting an issue in front of the committee, and the lack of pressing issues regarding GE fish (OPP-1). A food policy consultant said

the only possible way to get parliamentary scrutiny is to convince House of Commons committee chair to hold hearing on it and call witnesses. The architecture of our so-called democracy fuels the capacity of Government when they want to bury these kind of decisions deep in regulatory architecture of the system and make it almost impossible to pull it out. (ACAD-2)

NDP MP Atamanenko commented that there won’t be any controversial studies regarding biotechnology-produced animals in the Agricultural committee as the agenda is set by the Conservatives (NDP-A). After looking at Private Members Bill C-474 the Agriculture committee undertook a biotech study. The study had been interrupted by an election and as a Conservative MP stated, it wouldn’t be fair to new committee members to release a report summarizing information and proposing recommendations with respect to a study in which they did not participate (CMP). A summary of what the Committee had heard was appended to *Growing Forward 2*. Atamanenko said the summary report included in *Growing Forward 2* was an accurate reflection (NDP-A).

Limitation to Proceedings going ‘In Camera’

Transparency and accountability under the current Government was difficult according to four participants, because controversial topics are discussed in-camera where there is no record. A Liberal MP stated that those in power want to control the message coming out and that increasingly light and fluffy issues are driven in-camera (LMP-2). A MP from the opposition said that the biggest barrier is that the Government suffers from ideological paranoia and that anytime anything that is contrary to their ideology comes up they go in camera. The MP stated “Canadians know that now - at least I’m hoping they do” (OPP-2). NDP MP Atamanenko stated he firmly believed that this Government didn’t want good healthy democratic debate in committee. He had tried to introduce a motion to put a moratorium on GE alfalfa which the Conservatives immediately moved to a meeting in camera “so that there would be nobody following the proceedings” (NDP-A).

A Conservative MP provided an alternative perspective, saying that it was an unfounded accusation that committees go in camera too often. The MP said that the vast majority of committee work is done in public, is broadcast on CPAC, is sometimes televised, and the meetings’ minutes can be accessed by the public through the internet. The MP said that committees move in camera for two main reasons: to discuss committee business that has to do with the administration of the committee and to review and finalize the report it’s about to write, which is confidential until it is tabled in Parliament. The MP also said there are times when witnesses are called and where the committee does visits and those are not in camera (CMP).

4.2.7. A Dramatic Decline in Civil Servant - Public Interaction and Communications Flow

A dramatic decline in civil servant public interaction and communications was also noted by four participants. This included the muzzling of Federal Government scientists (NDP-J; NDP-A), resource cuts (NDP-J), and fear of repercussion. A reporter observed that decisions about when Federal Government scientists can talk to journalists appear to be made by political staff in ministers’ offices rather than communications specialists in the bureaucracy (JOUR). A Liberal MP said all departments fell into general secrecy about how they operate and the bureaucracy tends to keep things tight and do not want to share information for fear of repercussions (LMP-2).

4.3. Conclusion

This chapter identified seven common themes that emerged from interviews with respect to the transparency and accountability of Federal decision-making processes, and institutions concerning biotechnology-produced animals. A majority of participants discussed the amount of information made publically available. Most participants pointed out inadequacies in the current policy and regulatory framework. Most interviewees also suggested that there is a lack of political will to ensure transparency. Just over half of interviewees hypothesized that this could be due to the Federal Government's biased agenda towards biotechnology and that transparency appeared to be a growing problem due to declining avenues for public participation and reduced consultative initiatives. A few participants stated transparency appeared to be a growing problem due to a disempowered Parliament and a dramatic decline in public servant interactions and communications.

Chapters 3 and 4 provided examples of limitations to transparency surrounding the regulation of GE crops. These issues still exist for biotechnology-produced animals as a similar regulatory framework is used. These limitations will be explored further in the next chapter.

The next chapter provides an analysis of how the major themes from the interviews align with major themes from the literature. It discusses current issues with biotechnology-produced animals that highlight the diminishing transparency and accountability of the Canadian Government and the biggest institutional impediments to transparency and accountability.

Chapter 5: An Analysis of Limitations to Federal Transparency with Respect to the Human Consumption of Biotechnology-produced animals

5.1. Introduction

Chapters 2 and 3 revealed the limitations to transparency in the Federal Government's decision-making processes and institutions involving the manufacture, importation and sale of a biotechnology-produced animal for human consumption through an extensive review of secondary literature. These limitations were further explored through primary interviews (as discussed in Chapter 4). This chapter analyzes those limitations to transparency both within and external to the regulatory process. It includes an analysis of (1) the confidential nature of the regulatory processes (2) the assessment of science-based risks (3) the risks and impacts not taken into account through the regulatory processes and (4) the ability of interested parties to review the regulatory processes. This chapter concludes with a discussion of external constraints on Canada's regulatory system.

5.2. Limitations to Federal Transparency Regarding Canada's Regulatory Processes to Manufacture, Import and Sell a Biotechnology-Produced Animal for Human Consumption

The two major steps in Canada's regulatory process to approve a food product that is, or contains, material derived from a biotechnology-produced animal are pre-market notification under the *New Substance Notification Regulations* (Organisms); and Health Canada's pre-market safety notification under the *Novel Food Regulations*. Limitations to transparency surrounding Canada's regulatory processes to assess the human consumption of a biotechnology-produced animal arise from the confidential nature of the regulatory processes; the assessment of science-based risks; the scope of science-based risks; and the ability of interested parties to review how decisions are made and to review and participate in shaping the regulatory processes.

5.2.1. The Confidential Nature of the Regulatory Processes

The Federal Government restricts and releases limited information on applications going through the regulatory processes. The reason given is that they contain confidential business information (CBI). This affects transparency surrounding the manufacture, import and sale of a

biotechnology-produced animal for human consumption. Aside from CBI, as stated in the Royal Society of Canada’s Expert Panel Report on the Future of Food Biotechnology

The amount of information the regulatory departments choose to disclose from the application and approval process is not set by any formal regulations. Rather, it is a policy judgment that seeks to balance the interests of industry against the desire for transparency in the regulatory process. (The Royal Society of Canada, 2001, p. 213)

Chapter 3 and 4 discuss limitations to transparency surrounding foods that contain plants with novel traits (PNT aka GE plant). Table 5.1 compares Canada’s regulatory process regarding the human consumption of a biotechnology-produced animal to that of a food product that is or contains material from PNTs. It compares the confidentiality regarding the submission, assessment and final decision. It also includes voluntary initiatives regulatory departments have come up with to increase transparency through the regulatory processes.

Table 5. 1. The Federal Regulatory Process regarding the Human Consumption of Biotechnology-Produced animals compared to Plants with Novel Traits (PNT)

	Plants with Novel Traits (PNTs) for Human Consumption		Biotechnology-Produced Animals for Human Consumption		
	Concurrent		Stage 1	Stage 2	
	Pre-market Notification for Manufacture, Import or Sale	Pre-Market Safety Notification	Pre-market Notification for Manufacture, Import or Sale (biotechnology-produced fish)	Pre-market Notification for Manufacture, Import or Sale	Pre-market safety notification
Act and Regulations	Food and Drugs Act and Regulations	Food and Drugs Act and Regulations, Novel Food Regulation	Fisheries Act and Regulations, CEPA 1999, NSNR (Organisms), Environmental Assessment Regulations (Proposed)	CEPA 1999, NSNR (Organisms), Environmental Assessment Regulations (Proposed)	Food and Drugs Act and Regulations, Novel Food Regulations
Department in Charge	CFIA	Health Canada	Department of Fisheries and Oceans	Environment Canada, Health Canada for Proposed EARs	Health Canada

	Plants with Novel Traits (PNTs) for Human Consumption		Biotechnology-Produced Animals for Human Consumption		
	Concurrent		Stage 1	Stage 2	
Information released on Submission	Voluntary Notice of Submission. Comment period (posted on CFIA/HC websites)	Voluntary Notice of Submission. Comment period (posted on CFIA/HC websites)	Unknown	Confidential *	Unknown
Assessment Period	Unknown	Health Canada must respond within 45 days, and then has 90 days to issue a decision.	Unknown	Unknown	Unknown
Information released on Assessment Process	Unknown	Unknown	Unknown	Confidential, Risk Assessment Summaries posted on Environment Canada's website (voluntary)	Confidential
Decision posted (if approved)	**	Summary of decision document on Health Canada website	Unknown	Canadian Gazette (mandatory for NSNR), Approvals are posted on Environment Canada website (voluntary)	Summary of decision document on Health Canada website

Source: adapted from CFIA (2012e)

* According to the *Guidelines for the Notification and Testing of New Substances:(Organisms)* “Under section 313 of CEPA 1999, any person who provides information to the Government in support of a New Substances Notification may, at the same time, submit a written request that information be treated as confidential” (Government of Canada, 2010, p. 90). **Decisions regarding both the authorization for environmental release of PNTs and their use as livestock feed ingredients are also accessible from the Canadian Node of the Biosafety Clearing-House

As noted in Table 5.1., departments and agencies with regulatory authority have undertaken voluntary initiatives to provide information on applications going through the notification processes. These consist of the CFIA and Health Canada's Notice of Submission Project (as discussed in Chapters 3 and 4). A representative of Environment Canada added the department takes the time to make the assessment reports more readable and less technical and that, due to CBI, the applicant needs to approve what information gets included in the published report

before Environment Canada can post it. The representative also stated that the risk assessment summary may not be immediately posted on Environment Canada's website and could, in some cases, take several years before being published (PS-1).

The CFIA and Health Canada have a voluntary Notice of Submission initiative for food products from plants with novel traits (PNTs). One of the reasons the Notice of Submission was developed was "to support the commitment to achieve greater openness regarding product information made by the Government of Canada in its responses to the Royal Society of Canada's (RSC) Expert Panel Report" (CFIA, 2009a). According to Canadian Biotech Action Network's (CBAN) coordinator, the voluntary system was set up by Croplife, a biotech trade association. The coordinator added

The RSC report was looking to the future of regulations, well the future food are GM pigs and fish, and the Notice of Submission totally fails to address that, we're right back where we were before Notice of Submission! CBAN tried to say at the time [it was being created] that it was a joke. (NGO-1)

The initiative does not have a clear mechanism for considering incoming comments (Andree & Sharratt, 2004). It is also the only method set up by regulatory agencies for interested stakeholders to obtain information on applications going through the regulatory process.

A Notice of Submission initiative has not been set up concerning applications to approve biotechnology-produced animals for manufacture, import or sale for human consumption. The initiative was set up between Health Canada, the CFIA, and Croplife and its members. Croplife represents companies involved in GM crop development. The institutions involved in animal biotechnology are not represented by Croplife. With regard to animal biotechnology a Federal Government official who works in the area of food and health policy said that the Government was only dealing with a few "companies, universities, things like that so they don't have the same type of organizations like Croplife, umbrella organizations" (PS-2).

Aside from the voluntary Notice of Submission Initiative and the posting of risk assessments information on applications is not released until after a decision has been made. It is unclear why information on applications that were retracted or not approved cannot be accessed by interested parties, other than concerns about a potential overload of information and to protect business interest. Having access would increase transparency and accountability in the regulatory process by permitting comparison of a negative decision to a positive one. As discussed in this chapter, it is difficult to find a listing of novel food submissions and decision documents to

figure out whether every application that has been submitted to Health Canada has been approved for human consumption and whether applications have been retracted.

Health Canada posts decision documents on its website for novel food that have received approval through Health Canada's pre-market safety assessment (Health Canada, 2012a). The length of time it takes for the decision documents to get posted online can limit transparency. The product could theoretically be on the market shelves before the decision document is posted. As of December 2012 the listing of Novel Food Decision on Health Canada's website contained approximately 200 approved products. When the website was updated in October of 2012 the decision dates for the last two decision documents posted on Health Canada's website were April 27, 2011 and April 13, 2011. As of December 12, 2012, the website was last updated December 7, 2012 (Health Canada, 2012a). The updated version of the website contained 16 additional approved products, with decision dates ranging from June 2011 to June 30, 2012. A decision document was not provided for any of these 16 additional approved products (Health Canada, 2012a). This is the *only* method for a Canadian citizen to obtain information concerning the submission or approval of an application for a food product that contains biotechnology-produced animals. Right to Know legislation can be used, but, as stated, the application itself is confidential and limitations to right to know legislation noted through the literature and through interviews might result in information not getting received until after a product is on the shelves.

The amount of information provided in decision documents is also not an exact science. Some decisions documents give the notice of safety assessment and summarize Health Canada's safety assessment while others provide novel food information, consisting of a summary of the notification from the applicant and Health Canada's evaluation (Health Canada. 2011d; Health Canada. 2010e). As novel foods cover a broad range of products, through the decision documents it is also not always clear whether the novel food product that was approved had been derived through modern biotechnology. Furthermore, not all of the products that receive approval will reach the market (CMP). There is nothing set up to show when a novel food that contains GE material has entered the market for the first time and no mandatory method like a labeling standard to identify food products that are or contain GE material.

Health Canada's website states "To date, Health Canada has reviewed over 81 novel food submissions" (Health Canada, 2012d). Although this section of the website was updated in 2012, it did not update the number of novel food submissions. According to the Novel Food Decision

section on Health Canada's website Novel Food submissions reviewed by Health Canada surpassed 81 in 2006 (Health Canada, 2012a). This leads one to question how many more novel food decisions have been made.

Interestingly, a section on the CFIA website entitled *Animals and Animal Products Derived Through Modern Biotechnology: Roles and Responsibilities of the Government of Canada* states "No biotechnology-derived animals have been approved for release into the Canadian environment or for food. To date, the Government of Canada has not evaluated any requests for food use approval or environmental release of fish derived from biotechnology" (CFIA, 2012a). As of December 2012, this section on the website was last updated April 19th, 2012. The website does not mention if a request had been submitted for any animal besides fish. The website also does not state that the University of Guelph received approval for the manufacture and import of the EnviropigTM as of November 26, 2009 (Environment Canada, 2012).

It is not mandatory for regulatory departments to release information during any of the regulatory processes listed in Table 5.1. The applicant approves the information that gets released through voluntary initiatives. Examining risk assessment documents, decision documents, or attempting to access information through right to know legislation or the court system are the only ways for an interested stakeholder to obtain information on the outcome of an application for a biotechnology-produced animal that has gone through one of the regulatory processes described in Table 5.1.

An issue regarding the confidential nature of the application process concerns the lack of information the government releases, proprietary or otherwise. Opportunities exist under the regulatory framework that would allow regulatory departments to cater to the interest of applicants, the scientific community, or the public, as shown through the voluntary initiatives described above. A concern raised in the Royal Society of Canada's Expert Panel report on the Future of Food Biotechnology (2001) was the need for a regulatory balance between building a relationship with the biotechnology industry and having an open regulatory process.

The Expert Panel had questioned senior managers from Canadian regulatory departments about their

handling of the issues of transparency and confidentiality in dealing with applicants for licensing of new biotechnology. Their responses uniformly stressed the importance of maintaining a favourable climate for the biotechnology industry to develop new products

and submit them for approval on the Canadian market. If the regulatory agencies do not respect industry interests in protecting the confidentiality of product information as well as data obtained from extensive health and environmental testing, industry in turn will be deterred from engaging in the regulatory approval process. (The Royal Society of Canada, 2001, p. 213)

The Expert Panel Report stated that several managers “referred to the importance of maintaining a relationship of trust between industry and the regulators”. The managers had argued “Only in an atmosphere of trust... can Government and industry work together in the cooperative way necessary to generate the product and test data required for the protection of public safety” (The Royal Society of Canada, 2001, p. 213). The Expert Panel reported that the concern with industry development was understandable but highlights an aspect of the regulatory conflict:

The conflict of interest involved in both promoting and regulating an industry or technology... is also a factor in the issue of maintaining the transparency, and therefore the scientific integrity, of the regulatory process. (The Royal Society of Canada, 2001, p. 213, 214)

The report also noted that

In effect, the public interest in a regulatory system that is “science based” - that meets scientific standards of objectivity, a major aspect of which is full openness to scientific peer review - is significantly compromised when that openness is negotiated away by regulators in exchange for cordial and supportive relationships with the industries being regulated. (The Royal Society of Canada, 2001, p. 214)

The need to protect proprietary information makes it important that there is trust in the system and that information is being provided on regulatory processes including the assessment of risks.

5.2.2. The Assessment of Science-Based Risks

The processes through which Federal regulatory bodies approve a biotechnology-produced animal for human consumption assess science-based risks. Balancing the interests of applicants with the ability for interested parties to review the scientific data used in assessments as well as how the data is assessed are important when considering transparency and accountability in a science-based regulatory framework. Transparency regarding the assessment of risks during the approval processes for biotechnology-produced animals for human consumption is limited by: (1) the ability for interested parties to obtain information on how applications will be assessed

for risks through regulatory processes and; (2) the independence, objectiveness, and quality of the science used in the assessments.

The Assessment Process

The degree of transparency regarding the manufacture, importation and sale of a biotechnology-produced animal for human consumption is limited by the ability of the Federal Government's regulatory bodies as well as third parties to review how and what risks are being assessed. For a food product from a biotechnology-produced animal to be approved for human consumption, as shown in Table 5.1., pre-market notifications must be made according to NSNR (Organisms) under CEPA 1999 as well as the Novel Food Regulation in the *Food and Drugs Act*. How a biotechnology-produced fish would be assessed is being developed, as are Health Canada's proposed Environmental Assessment Regulations (EARs).

New Substance Notification Regulations (Organisms)

As of December 2012 the Enviropig™ is the only biotechnology-produced animal that has received approval for manufacture, import and sale through the NSNR (Organisms) under the *Canadian Environmental Protection Act, 1999* (CEPA) 1999. The NSNR examine whether the product is toxic under the criteria set out in section 64 of CEPA 1999.⁸ The NSNR risk assessment evaluation does not “include an assessment of the potential human exposure and health risks associated with the use of the notified organism in products derived from it in or as an item that falls under the purview of the *Food and Drugs Act*” (Environment Canada, 2012). For PNTs, as shown in Table 5.1., approval for manufacture, import, sale and human consumption is done concurrently. The Enviropig™ application for manufacture, sale and import was submitted in January of 2009 and received approval in November (Environment Canada, 2012). An application for human consumption was submitted in April 2009 and as far as the research can tell, a decision has not been reached (Mann, 2011).

Through the NSNR (Organisms) the manufacture and import of the product can happen without the examination of potential risks to the food supply. This is worrisome as there is

⁸ “In accordance with section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health” (Canadian Environmental Protection Act, 1999).

potential for GE animals approved for manufacture and import to be unintentionally introduced into the food supply. The risk assessment summary for the NSNR concerning the Enviropig™ stated “[I]t is conceivable that the escape of transgenic pigs in those regions where wild boar populations exist may result in the introduction of the transgene into the feral wild boar gene pool with unknown consequences” (Environment Canada, 2012).

The risk assessment summary concerning the Enviropig™ recommended a significant new activity (SNAc) provision “based on the uncertainties regarding possible environmental impacts of the notified organism in activities outside the scope of this assessment” (Environment Canada, 2012). Significant New Activity Notices were not designed specifically for contamination from biotechnology-produced animals. Canada does not have a unique system of traceability for GE animals.

Federal Guidelines for the Safety Assessment of Novel Foods

As of October 2012 Health Canada has not released a decision on the University of Guelph’s application for the human consumption of a biotechnology-produced animal, the Enviropig™. This notification is the only one Health Canada has confirmed it has received. How Health Canada would conduct its safety assessment is unknown as safety assessment criteria are still under development (Health Canada. Food Directorate Health Products and Food Branch, 2006). The Government of Canada’s January 2002 Progress Report regarding the “Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report” stated Health Canada was in the process of drafting *Guidelines for the Safety Assessment of Livestock Animals and Fish Derived from Biotechnology* (Government of Canada, 2002a, p. 13). The Government’s December 2002 Progress Report stated they were working on developing and publishing Volume III on the safety assessment of foods derived from animals (Government of Canada, 2002b, p. 18). Information concerning updates to the guidelines regarding biotechnology-produced animals has not been released since 2006.

A Federal Government official who works in the area of food and health policy said that the science-based guidelines are currently being worked on and could not say when they would be finished (PS-2). The official stated that theoretically, if Health Canada was doing parts of an assessment before having guidelines finalized, the department would be doing it under Codex Alimentarius guidelines. The official also said that guidelines being developed would not be that

different from Codex Alimentarius and to remember that guidelines documents are also living documents (PS-2). Although they do not have the force of law guidance documents are important as they “set out how a department, regulatory authority or other body applies laws and regulations under their jurisdiction. They provide transparency in decision-making and fill in details sometimes missing from the strict nature of legal language in laws or regulations” (Health Canada, 2010b).

It can be surmised that until the safety assessment criteria for the human consumption of biotechnology-produced animals are developed and information is released on them, guidance information will not be made available to the general public regarding how biotechnology-produced animals will be assessed for human consumption. The assessment process to approve a biotechnology-produced fish for manufacture, sale or import or for human consumption is also unknown.

The Lack of Environmental Assessment Regulations (EARs)

As stated in previous chapters, Health Canada was also given authority to make Environmental Assessment Regulations (EARs) to replace the NSNR with respect to new substances in products under the Food and Drugs Act. Health Canada website, under “Processing a Novel Food Notification/Submission in the Food Directorate”, last updated in 2006, states that “In some cases, an environmental assessment of novel foods is conducted under proposed Environmental Assessment Regulations” (Health Canada, 2006f). As of October 2012 Health Canada’s website, last updated in February 2011, states that it was anticipated the proposed EARs would be pre-published for comment in the *Canada Gazette*, Part 1 in 2011 (Health Canada, 2011c).

Summary

According to the Federal Government’s Progress Reports concerning the *Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel* (2001) all of the regulatory processes described in the above section were supposed to be completed by now. The last progress report released in 2005 included a section on genetically modified animals and on tasks that had yet to be completed regarding the regulation of food products from these animals (Government of Canada, 2005b). It is not known why the Government stopped producing reports, especially given there was no indication in the 2005 report that it was going to

be the final report. While following up with progress reports is not mandatory, it was a voluntary method for regulatory departments to inform interested stakeholders on the progress of recommendations made by the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology.

As discovered in the literature review and verified through interviews, an assessment of the decision-making structure is hard to conduct due to the lack of information being released by the Federal Government and the ability for members of the public to find pertinent information on the topic. Information released by the Government regarding the application process and assessment of risks has been inaccurate or is not up to date. The last updates and consultations for both Health Canada's *Guidelines for the Safety Assessment of Novel Foods* as well as the *Environmental Assessment Regulations* took place in 2006. How data packages will be assessed for biotechnology-produced animals under EARs and under the current guidelines is unknown. It is also unknown how the concepts like substantial equivalence and novelty would apply to GE-animals. Whether NSNR (Organisms) would still apply to biotechnology-produced animals after EARs are created is also unknown, as is whether the EARs would fall under the *Food and Drugs Act* or the *Canadian Environmental Protection Act*.

It should be noted that it is challenging to keep websites up-to-date. It is also difficult for interested parties to obtain information on regulatory processes when Government websites provide contradictory information. Health Canada's voluntary Interim Policy on Cloned Animals (2001) (as discussed in chapter 3) also provides an example of the regulatory process not being suitable for food products from animal biotechnology. Moreover, technology is speeding ahead of regulations. Things have become less transparent simply because nothing is set up specifically for biotechnology-produced animals. The development of biotech food products are outpacing updates to regulations.

Concerns about the Independence, Objectiveness, and Quality of the Science

As stated in Chapter 3, the processes through which Federal regulatory bodies assess foods produced through modern biotechnology (GE foods) are limited to the assessment of science-based risks. The Royal Society of Canada's Expert Panel Report on the Future of Food Biotechnology (2001) noted that "the claim that the assessment of biotechnology risks is 'science

based' is only as valid as the independence, objectivity and quality of the science employed” (Royal Society of Canada, 2001, p. 212). The Expert Report also stated

This issue was raised as a concern by many of the parties who made submissions to the Expert Panel. It is generally framed in terms of public trust in the objectivity and disinterestedness of the scientists who develop, test and regulate biotechnology products. But it also concerns the process by which the underlying science used to assess GM products is made transparent to independent validation. (Royal Society of Canada, 2001, p.211)

Conflicting Regulatory Roles

The Royal Society Report recommended that “All the regulatory departments involved in the regulation of food biotechnology should seek to separate institutionally as much as possible the role of promoter from the role of regulator” (Royal Society of Canada, 2001, p. 212). As discussed in Chapter 3 and 4, the CFIA’s role to regulate GE crops and GE feeds has been critiqued (NDP-J; Royal Society Report 2001). Environment Canada, not the CFIA was given authority over the pre-market notification for manufacture, import and sale of biotechnology-produced animals. Environment Canada was given the authority to regulate the products under the NSNR because no regulations were in place for biotechnology-produced animals, not specifically to avoid the CFIA’s noted conflict of interest. The CFIA still hold responsibility over biotechnology-produced animals, for example through the Food Rulings Committee described in Chapter 2.

An Unconstrained Regulatory System for Genetically Engineered Animals

Efforts to liberalize the regulatory processes for GE foods can impede transparency and accountability. Former MP Wasylycia-Leis said that the current and previous Federal Governments had put the onus of scientific health studies onto the industry itself “even though they have a vested interest in one outcome” (NDP-J). A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that GE seeds were given “extra points” to give them a boost in getting certified when they first entered the market.

When GE crops were first coming on line, before crops could be approved the seeds had to be certified. Because GE seeds were new on the scene they were scored differently. They were given extra points than the regular conventional seeds to give them a boost into the marketplace. There are all these ways GE foods get promoted that fall under the radar because no one knows or understands how these things work unless you are an insider. It just happened that a friend of ours was doing work on seed certification and

was talking to a farmer who mentioned something about GE seeds getting certified through the same process but starting out higher on the points system. (ACAD-1)

Attempts have also been made to streamline the regulatory approach to animal biotechnology such as CFIA's Animal Biotechnology Focus Group Meeting held in March of 2004. Members of academia Lucy Sharratt (also coordinator of CBAN) and Peter Andree wrote that

Given that no regulatory approach exists yet, an emphasis on streamlining is entirely inappropriate. This demonstrates the willingness of biotechnology regulators in Canada to look for business-friendly approaches before fully addressing public concerns. (Andree & Sharratt, 2004, p. 21)

A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said "They are trying to make it as streamlined, as easy as possible, for these products to be released into the environment and into the marketplace. They figure the return on the investment is worth the risk to the public and to consumers" (ACAD-1).

It is unknown whether the onus of scientific health studies is placed on the industry regarding approving biotechnology-produced animals for human consumption (like GE crops, as discussed in chapter 4.3.2.) or whether the animals would be promoted through Federal Government processes that fall 'under the radar' to ease their introduction onto the market.

Lack of information about the Federal Government's Assessment of Risks

The last available information (2006) noted that Health Canada was still developing safety assessment criteria with respect to the approval process of a biotechnology-produced animal for human consumption (Health Canada. Food Directorate Health Products and Food Branch, 2006). Through previous examples of Health Canada's assessment process we do know that the use of substantial equivalence, especially as seen in the approval of Smartstax™ maize (see chapter 3) does not look for novel risks created by evolving biotechnology processes. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO referred to Professor Ann Clark's work on some of the studies Health Canada was supposedly doing on feeding studies on GE crops to see if they were toxic or having toxic effects on animals. The specialist stated that professor had written the concept of "don't look don't find" was being utilized by the government. She elaborated

What they do is very conventional nutritional studies and they don't look at specific things that are connected to the process which is the way you integrate new genes into a

genome and looking for possible mutations and possible long-term effects etc. You can safely assume that things are not dangerous but in fact we know that that's not the case. (ACAD-1)

She connected these findings to GE animals:

If you compared two animals to each other they will look the same, they will have the same characteristics essentially it becomes difficult to figure out what is different about them. It's impossible to prove what isn't there – it's impossible to start studying something when you don't really know what you're looking for. (ACAD-1)

The way the Federal Government examines data and assesses risks that are in the notification processes is a matter of some concern; sample size and the life span of an animal make testing biotechnology-produced animals difficult when compared to a genetically engineered crop. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that there were a variety of issues with biotechnology-produced animals that don't apply for GE crops “you're dealing with a different level of genetic modification with much more complex genomes, much more unpredictable consequences” (ACAD-1). An NGO representative who had attended the United States of America's Food and Drug Administration hearings on the AquaAdvantage® salmon stated “the most glaring and obvious problem with the data that AquaBounty has sent to the Food and Drug Administration was that they were able to submit six salmon, all the others had die. They admit it in their own evidence” (NGO-2). It is unknown what Canadian regulatory departments would consider a large enough sample size to assess biotechnology-produced animals for human consumption and the length of time needed to conduct an assessment. The French group of Gilles-Eric Seralini has shed light that the Health Canada's current assessment process is too short of a time period to properly assess for harmful effects on the consumption of GE maize (Seralini, et al., 2012). The appropriateness of time periods for assessment processes for biotechnology-produced animals is unknown.

This is worrying as AquaBounty Technologies Inc issued a statement accusing the US government of unjustifiable delays in licensing its AquaAdvantage® salmon. A representative of the company stated the approval is being impeded by reasons other than the science-based evaluation of the application (AquaBounty Technologies Inc, 2012b). If AquaBounty has submitted or was going to submit an application for human consumption to Canadian regulatory authorities there is potential for the company to pressure Health Canada to reach a decision. Also Health Canada has not reached a decision on the Enviropig™ application, submitted in April of

2009. As a result, the University of Guelph could start pressuring for action and approval if it hasn't already.

5.2.3. Limitations surrounding the Assessment of Risks / Risks and Impacts not taken into account through the Regulatory Processes

It would be unrealistic to think that every risk, impact and concern that has been raised in the literature and interview should be taken into account during the regulatory processes for biotechnology-produced animals described in Table 5.1. One health policy government representative stated the assessment processes should remain science-based so that politics are not involved in safety regulations (PS-2). The degree of transparency and accountability in the science-based regulatory system for biotechnology-produced animals is affected by (1) potential science-based risks not being examined (2) risks that go beyond the science-based risks being assessed are not taken into account through other Government platforms / avenues and; (3) an inability to trace products in the food system.

Participants and literature raised concern that science-based risks arising from the consumption of GE products outside of toxicity and allergenicity are not known and are not being looked for. For example, processes specifically designed to identify and assess risks from the manufacture, import and sale of biotechnology-produced animals for human consumption do not exist. The Federal Government has not undertaken long term health studies regarding GE foods. The ability to do long-term human health or scientific studies have been impeded by the fact that GE foods are not labeled, making it hard to find a sample population.

The regulatory framework to approve a food product that is or contains material derived from a biotechnology-produced animal limits the risk assessment to science-based risks and does not examine social or economic risks, including the level of consumer acceptance and impact to export markets. The CFIA website under “Regulating Agricultural Biotechnology in Canada: An Overview” states

The Canadian Food Inspection Agency and Health Canada regulate for safety and efficacy of these products, but are not responsible for evaluating need. The issue of whether or not these products are ‘necessary’ is left to the market place to determine. (CFIA, 2012e)

A similar regulatory framework is used for biotechnology-produced animals. The assumption that risks will be looked at or taken into account elsewhere leads to the potential for risks to be overlooked or remain unconsidered. For example the ability to ‘let the market decide’ is limited if consumers cannot identify what food products contain genetically engineered materials.

Concern has also been raised over the lack of Canadian regulatory and traceability processes for food products from biotechnology-produced animals that receive approval in the international community. For example, scientists at the Department of Fisheries and Oceans raised concern that if the United States approves the AquAdvantage® salmon Canada doesn’t have a system of traceability set up (JOUR). A spokesman from large Canadian food distributing company also raised concern that there is no traceability system in place to determine whether a meat product comes from a cloned animal (IND). Traceability measures for research animals have also failed, as seen through the unintentional introduction of the Enviropig™ onto the market in 2002 (discussed in Chapter 3).

5.2.4. Constrained Ability of Interested Parties to Review the Regulatory Process

Safety testing, science-based regulation, and the scientific process itself, depend crucially on widespread trust in a body of scientists devoted to the public interest and professional integrity. If instead, the starting point of a scientific product assessment is an approval process rigged in favour of the applicant, backed up by systematic suppression of independent scientists working in the public interest, then there can never be an honest, rational or scientific debate. (Bardocz et al., 2002)

There is a limited ability or inability for interested parties to review, participate in and influence the regulatory process surrounding the assessment of biotechnology-produced animals for human consumption through (1) peer review, (2) review through voluntary initiatives, right to know legislation and the court system, (3) review through the House of Commons and parliamentary committees and; (4) review of the policy framework. Influence is limited as evidenced by the use of the CBAC and RSC the focus of reviews and the lack of public debate.

Lack of a Peer-review Process to assess scientific data

The lack of a peer-review process regarding how biotechnology-produced animals are assessed for human consumption was raised in interviews and in literature. The New Democratic Party of Canada’s Dissenting Opinion attached to the Standing Committee on Agricultural and Agri-

Foods Report *Growing Forward 2* (2012) states the need for the creation of an independent body to peer-review relevant scientific data (Standing Committee on Agriculture and Agri-Foods, 2012, p. 80). Health Canada's proposed to have an external expert sit on the Food Rulings Committee (Government of Canada, 2001, p. 5). The need for another expert panel like the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology was raised by a spokesman from a large Canadian food distributing company (IND). None of these initiatives have been implemented.

The ability for independent review of the regulatory process is especially important due to concerns over conflicting roles of regulatory departments (The Royal Society of Canada, 2001). The CFIA website states that, "it is common in the sciences for data to be reviewed by scientists other than those who produced the data. This is done so that quality standards are followed and to allow for shared judgments of difficult issues - this co-operative approach also serves the goal of the reproducibility of regulatory decisions (CFIA, 2012f).

If scientists in Health Canada, Environment Canada, or the CFIA are producing their own data through the assessment of data submitted by applicants, this arms length approach is presumably in place to ensure reliable information. If the departments are not producing their own data, it means that regulatory processes only rely on data being submitted by applicants, which is worrisome (as discussed in chapter 4). It is unknown whether Health Canada would produce its own data concerning biotechnology-produced animals.

Review through voluntary initiatives, right to know legislation and the court system

Access to information is limited with respect to the regulatory processes through voluntary initiatives (as discussed in chapter 5.2.1), right to know legislation and through the courts. For example the Auditor General's Office has voluntarily put on its website an online catalogue to review petitions, but the information that can be released is limited (as discussed in chapter 2). As well, Canadian citizens who submit petitions must have knowledge about what they are looking for, which is a constraining factor, particularly with respect to biotechnology-produced animals since very little information gets released (as discussed in chapter 2). Literature and interviews have also revealed shortcomings in public access to information through right to know legislation, and the court system (i.e., particularly with respect to receiving responses in a timely and cost-efficient manner). Effective transparency also goes beyond the disclosure of

documents through Freedom of Information legislation and the Access to Information Act, as discussed in Chapter 1. As a result of the voluntary nature of initiatives, and a reliance on right to know legislation and courts, it is very difficult to hold decision-makers accountable.

Limited Review through the House of Commons and Parliamentary Committees

As of October 2012, Private Members Bill and motions regarding GE foods have not passed in the House of Commons and the House of Commons had not completed a broad review of the assessment of food products derived from biotechnology. The Standing Committee on Agriculture & Agri-Food's study on the status of the Canadian biotechnology sector (2010-2011) was stopped it could release a full report (as discussed in Chapter 3). The Standing Committee on Health's study *Labeling of genetically modified foods and its impact on farmers* (2001-2003) was stopped before the Committee could finish conducting research. Both Committees formed after a Private Member's Bill was brought into the House of Commons. The Standing Committee on Health "agreed not to pursue the subject further" after hearing an update on the development of a voluntary labeling standard (Health Canada, 2006a). The AAFC's Committee was stopped due to an election, which a Conservative MP stated as being a rare situation (CMP).

Committee reports are divided by the responsibility and focus of the committee. For example the Standing Committee on Agriculture and Agri-Food study did not examine health and safety issues (NDP-A). The responsibility of critics in the House of Commons is also divided. Former MP Wasylycia-Leis said "when one person isn't responsible for all you can dilute it a bit sometimes, you leave things to the other critic" (NDP-J).

Review of the Policy Framework

The division of responsibility for regulating biotechnology-produced animals for human consumption has limited the ability for review of the entire regulatory structure as well as the policy framework. This is especially true as approvals and updates happen in a fragmented manner. Participants identified an issue as the lack of reviews, advisory bodies, public debate or consultations on the broader policy framework for GE foods. The overarching policy direction is not being openly critiqued through departmental or committee consultations or reviews.

Narrow Focus of Reviews

Public consultations and advisory bodies involved in the regulation of biotechnology have been criticized for being narrow in focus and for being “window dressing” as decisions had already been made surrounding the topics being discussed. Mitchell, a former member of the CBAC as well as members of the Royal Society of Canada’s (RSC) Expert Panel on the Future of Food Biotechnology stated they could only discuss a narrow range of issues (NGO-C; Royal Society of Canada, 2001). Mitchell said that the policy framework had already been decided and the CBAC could only provide advice on a narrow range of risks (i.e. little discussion of ethics) (NGO-C). In their report the RSC Expert Panel stated that discussions still had to take place beyond the scope of their paper (The Royal Society of Canada, 2001, p. x). These are examples of the narrow focus of past reviews. The Federal Government has not commissioned an external body to do a broad overarching critique on the chosen regulatory framework for the consumption of GE foods or biotechnology-produced animals. Whether it will is unknown.

Lack of Public Debate and Participation

There is no public consultation or review process for a research facility to become a commercial facility, for approval for the human consumption or manufacture, import and sale of a biotechnology-produced animal (as discussed in Chapter 5.2.1). Without public dialogue stakeholders do not have an opportunity to influence the outcome of applications and hold decision-makers responsible. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO, an NGO representative and Lucy Sharratt, CBAN’s coordinator all voiced frustration with attending consultations regarding biotechnology (as discussed in Chapter 4 (ACAD-1; NGO-3; NGO-1)).

When regulations are updated the consultation processes can be limited in scope (as discussed in Chapter 2). CBAN’s coordinator said that limiting the consultation’s focus to science-based risks means limiting the expert participants invited to those who understood the science behind biotechnology (NGO-1). These experts bring a focused interpretation of problems from which to base their policy-making decisions, an approach that does not take into account the ethical, social or political implication of the policies being considered which would allow for the involvement of a broader range of participants in the policy-making process. This approach prevents alternate perspectives and ideas from influencing Federal Government policy-making.

There is no public participation or consultations during the regulatory processes for biotechnology-produced animals described in Table 5.1 and it is minimal in the development of the regulatory framework for biotechnology-produced animals. For example a Federal Government official who works in the area of food and health policy stated that since guidelines are not a part of regulations, the consultation process for guidelines would consist of “one-step consultations” (PS-2). As well, the ability of the public to review potential risks to the food system depend on the information released concerning what is going on in research facilities.

The ability to critique the process has been constrained because advisory bodies have been shut down (Health Canada’s Public Advisory Committee (PAC), have been replaced (CBAC), or are for selected stakeholders (e.g., the pork value chain roundtable). Consultations are also either fragmented for specific updates to regulations, or focus on broader issues than biotechnology, like food safety (as discussed in Chapters 3 and 4).

There has never been a debate in Canada over the future of biotech animals for human consumption. Bureaucrats have had meetings with members of civil society but are restricted in the information they release and how they can responded to concerns or suggestions that are raised (NGO-2; NGO-1).

CFIA’s website, under “safety assessment process for Novel Foods and Agricultural Products of Biotechnology” under the heading “what about social aspects” states

The 1993 Federal Regulatory Framework for Biotechnology requires departments and agencies to consider "the prosperity and well being of Canadians" in the development of regulations, including provisions for public input into the development of these regulations. As a result, social and economic impacts are considered when decisions to establish regulations are made; this includes an analysis of immediate and long-term impacts. (CFIA, 2012f)

It does not appear that this has happened. The issues of making policies for the human consumption of food produced through biotechnology also emerged as a technical problem rather than a social question (as discussed in chapter 3). The need for public debate and consultation is evident as social and economic impacts from food products derived from biotechnology can change and evolve over time, especially with the introduction of biotechnology-produced animals.

5.3. External Restrictions to Transparency

Factors that influence the development of regulatory processes for biotechnology-produced animals include: (1) how biotechnology-produced animals are portrayed (not just how they are being regulated), (2) the ability to “let the market decide” and; (3) the lack of a unique policy framework and division of regulatory responsibility. These issues impact the transparency and accountability of regulatory processes.

5.3.1. Private-Sector Framing of Regulation

Companies, research institutes, and developers have control over the information that gets released regarding the biotechnology-produced animals that are developed in their research facilities, including any notifications and applications they have submitted to relevant Federal Government departments concerning those animals. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that if the majority of the animals in a research facility were mutated no one would know; the research facilities are confidential and Federal Government scientists and independent scientists are constrained in their ability to conduct additional tests to verify claims (ACAD-1).

Other than the mandatory labeling requirements that apply to all food products, the regulatory processes for the manufacture, sale, import and human consumption of biotechnology-produced animals do not assess the validity of claims made by the notifier regarding the benefits of their product(s) (Environment Canada, 2012). Furthermore the ability for the public or independent bodies to test these claims is limited due to laws surrounding proprietary information, the lack of Federal Government resources, and the fact that research facilities have been and continue to be directed by the biotechnology industry (i.e. through university partnerships) (Royal Society of Canada, 2001, p. 215; GP-1).

Government support in the public discussion of biotechnology

In both literature and interviews in this study, it was evident that the Federal Government has been promoting the use of biotechnology (as discussed in Chapters 3 and 4). Government websites and publications package biotechnology-produced animals as a continuation of traditional methods that have a long history of safe use (Government of Canada, 2008b). This

arguably does not accurately reflect the advances that have been made. Research participants and literature also raised issues with deciphering Federal Government bodies' uses of the terms novel, genetically engineered, biotechnology, genetically modified organisms, and genetic modification (Royal Society of Canada, 2001; NGO-3; GP-1; OPP-1; CMP).

BioPortal: A biased government website

The Government of Canada's website "BioPortal" was critiqued in interviews for being one-sided (NGO-C). The website refers to sustainable development as "the ability of producers and manufacturers to satisfy product needs of today while preserving the ability to meet those needs in the future" (Government of Canada, 2011b). This is an industry-friendly view of the term when compared to more common definitions such as the Brundtland Commission's which defines sustainable development as development that "meets the needs of the present without compromising the ability of future generations to meet their own needs" (United Nations. World Commission on Environment and Development, 1987). The sustainable development section of BioPortal also goes on to state that "Biotechnology and biotechnology-derived applications provide industries with tools to enhance the sustainability of products, thereby facilitating the attainment of sustainable development goals" (Government of Canada, 2011b).

Through the 1995 amendments to the *Auditor General Act* federal departments and agencies have to prepare sustainable development strategies and update them every three years. By creating a definition of sustainable development, departments can state a sustainable development strategy is encouraging the use of modern biotechnology in the food system. The BioPortal website also goes on to state

Even though biotechnology-derived applications may reduce manufacturing costs and improve profitability, there are many companies that rely instead upon traditional production methods, be it because they are unaware of biotechnology's industrial applications, or because they remain cautious of biotechnology use in industry...Biotechnology-derived applications are generally more environmentally friendly than existing industrial methods. (Government of Canada, 2011b)

The site fails to mention the role of organic farming methods in sustainable development. The website also states "the proper handling and labeling of genetically modified foods promotes social responsibility in producers and ensures that consumers can make informed decisions when

purchasing such produce” (Government of Canada, 2011b). Whether proper labeling is being used is hard to judge as there hasn’t been a review of the labeling standard.

Lack of Political will

Increases to transparency with regard to how much and in what manner the Government releases information are directed by the will of the governing political body as well as the ability and willingness of bureaucrats to identify where transparency is lacking and where it can be increased. As stated in Chapters 3 and 4 department and agency initiatives to increase transparency concerning GE foods have gone beyond their mandates to foster transparency and accountability.

Narrow Focus Regarding Food Safety

Participants also said that any Government efforts that are being directed towards increasing food safety and food safety measures do not extend to the process of genetic engineering. In other words, no specific food safety rules have been created that apply directly to GE foods. As resources are being devoted to food safety, the AAFC have held consultations to allow a percent, 0.1% or higher, of food to be contaminated with genetically modified (GM) foods that have not been approved by Health Canada for safe human consumption (AAFC, n.d., p. 3; discussed in 3.4.3). Health Canada’s regulatory assessment is also not set up to look for risks that could be introduced through the process of genetic engineering, as shown in the approval for Smartstax corn (discussed in chapter 3). Appendix A also reveals occasions that when GE foods are brought up in the House of Commons or media, the CFIA releases information on the confidence of or improvements to food safety. For example, in 2011 the same month NDP MP’s Fin Donnelly’s motion was tabled the CFIA announced they would strengthen food safety and transparency through a different method.

5.3.2. A Limited Ability to “Let the Market Decide”

The ability to “let the market decide” is based on explaining risks to consumers and having avenues for them to make decisions regarding whether they want to consume the products. How GE foods are framed, the lack of a public debate, the lack of a review of the effectiveness of the voluntary labeling standard, and the narrow scope of risks and impacts taken into consideration

before or after the food product is approved for human consumption impede the ability to “let the market decide”. One government representative said that food products should be assessed for safety risks, and that broader issues should be taken into account through other means (PS-2). Gauging consumers’ preference is limited if there is a lack of public information, review or debate and the only risks that are being identified by the Federal Government are science-based.

Currently, the only way to avoid GE food products is through buying organic foods. The ability to buy organic food as an avenue to avoid GE foods is affected by the potential of low level presence (LLP) of GE material (discussed in chapter 4.2.1.) and the potential for unintentional contamination. Organic foods can also be more expensive, which can affect the ability of consumers to choose whether they want to consume GE foods.

5.3.3. Lack of a Unique Regulatory Framework for Foods Derived Through Biotechnology

Public discussions are not being held about the creation of a unique regulatory framework for food products of biotechnology that take into account unconsidered risks in the current regulatory framework.

In the absence of a unique regulatory framework, transparency and accountability have become fragmented throughout the Federal Government departments and agencies and their various responsibilities and separate assessment processes. Furthermore, the current policy framework is not being reviewed for the ability to assess biotechnology-produced animals for human consumption. The division of responsibilities among Government departments and agencies also allows for conflicts of interest to exist in a way that is not obvious (i.e., the CFIA’s role as both promoter and regulator).

5.4. Conclusion

Limitations to transparency exist within and outside of the Federal Canada’s regulatory processes to manufacture, import and sell a biotechnology-produced animal for human consumption. These stem from the confidential nature of the regulatory processes, how and what risks are assessed during the assessment processes and the independence, objectiveness and quality of the science used in the assessment process, how the private sector frames the issue of GE food regulations, a limited ability to “let the market decide” and the lack of a unique regulatory framework designed for food derived through biotechnology resulting in a division of regulatory

responsibilities that lead to fragmented increases to transparency. The next chapter provides examples of existing and potential opportunities to increase transparency identified in interviews and through the literature.

Chapter 6: Opportunities for fostering Transparency

There is no better area to study in terms of lack of government transparency and accountability than these foods. (NDP-J)

6.1. Introduction

Despite the identified challenges, transparency could be fostered in Federal policies and regulations with respect to the human consumption of biotechnology-produced animals. Chapter two reviewed a number of mechanisms that could be used to increase transparency in the Federal Government if there was political will to do so. These approaches could be carried out through Federal Government institutions, non-government organizations (NGOs), private sector bodies, members of academia and the media. This chapter discusses additional avenues within and outside of government that could be used for fostering transparency based on primary interviews supplemented by the additional research of relevant literature.

6.2. Opportunities for Civil Servants and Elected Officials to Foster Transparency

Elected Federal Government representatives and public servants could use a number of avenues to enhance transparency including the release of Federal Government communiqués, information bulletins and reports. The public could be engaged through public consultations approaches or the establishment of expert panels. Members of parliament could use the House of Commons as a vehicle for increasing transparency, civil servants could take various initiatives and the ruling Federal Government itself could take a more active role in assessing and analysis the effectiveness of current regulations. All of this of course would require political will.

Federal Government Information Releases

Federal Government experts who are actively working on the biotechnology file could provide public reports about the state of affairs and challenges they are facing in a manner where trademarks and confidential information are not compromised (JOUR).

The Federal Government could also issue a new Progress Report concerning its *Action Plan of the Government of Canada in response to the Royal Society of Canada's Expert Panel Report Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in*

Canada (2001). The last progress report was published in 2005 and had action items and time lines concerning the creation of regulations for biotechnology-produced animals that, as of December 2012, still have not been reviewed.

Suggested avenues that would increase transparency regarding the regulation of biotechnology-produced animals in the Royal Society's Expert Panel Report on the Future of Food Biotechnology could be implemented (Standing Committee on Agriculture and Agri-Foods, 2012, p. 80).

Moreover, Federal Government department and agencies could review the information that it releases to the public outside of Access to Information (ATI) requests surrounding the regulatory processes to approve biotechnology-produced animals for human consumption. This includes information on the regulatory processes as well as individual applications. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that a great deal of information concerning decision-making can be released on the assessment of an application without giving away confidential information (ACAD-1). The Federal Government could provide this information if it wished to do so.

The Federal Government could also provide information to interested parties about all applications going through a pre-market notification process concerning a biotechnology-produced animal including those applications that were retracted or not approved. This would improve public understanding of the regulatory processes and would increase transparency and accountability in the regulatory process by permitting comparison of a negative decision to a positive one.

Federal Government releases could also include information that traced the production of biotechnology-produced animals that goes "right through the food system so the public is aware of what they're eating" (GP-1). Such a system could reduce the potential of allowing unapproved food items to enter the market. Through a system of traceability a system could also be developed to compensate farmers in the event that livestock became contaminated with biotechnology-produced animals (NDP-A). A system of traceability could even extend to the creation of a mandatory labeling standard specific to food products that contain biotechnology-produced animals. It should be noted that a process based labeling standard does exist in Canada for food products that have gone through irradiation.

Involvement of Non-state Actors in Consultation Processes and Third-Party Verification

The Federal Government could also hold forums on the future of food biotechnology in Canada that could clarify the Federal Government's agenda. There is a need for the Federal Government to consult with Canadians on its agenda and whether Canadians want to be part of unleashing the technology in the world (OPP-1). Providing the rationale for updating regulations to interested parties 'at the ground level' could address concerns that the function of updates is to allow the biotechnology industry to short cut the regulations (as seen with GE seed certifications, discussed in Chapter 5.2.2).

A Federal Government official who works in the area of food and health policy stated that the changing lay of the land regarding interest groups would make it hard for the Government to keep up with demand with regard to risk communication, especially as GE foods are being assessed on a case-by-case basis (PS-2). A food policy consultant said that the risk communication side often receives more attention by the Federal Government than consideration of the kinds of risks that might be deemed legitimate, and what mechanisms could be used to assess them (ACAD-2). The consultant maintained that the Canadian regulatory system asks a very limited set of questions regarding what kinds of risks are legitimate and what mechanisms are used to assess risk (ACAD-2). Consultations regarding biotechnology-produced animals could take place concerning both risk assessment and those risks that are taken into account in the regulatory processes. The consultant also suggested that the Federal Government could undertake a regulatory reconfiguration or regulatory pluralism approach "where the Government actively facilitates the interaction of non-state actors involved in designing and executing programs and policies" (ACAD-2).⁹

Public advisory or expert panels could be set up to review the current policy framework for the adequacy of its ability to assess new biotechnology products. It could also be critiqued to assess for past success in regulating biotechnology food products, including GE flax and cloned meat. The Federal Government could consult with interested stakeholders regarding current transparency initiatives with respect to regulatory processes, including the notice of submission project, decision documents, and the voluntary labeling standard. The Federal Government could also assess how unique regulations and policies for GE foods could be developed.

⁹This topic is discussed in the 2012 book Rod MacRae co-edited with Elisabeth Abergel entitled *Food System: Advocacy and Opportunity for Civil Society*.

The current framework could be critiqued through an Advisory Committee with a broader membership and mandate than that of the Canadian Biotechnology Advisory Committee (CBAC) which would allow it to explore ethical and social issues surrounding biotechnology-produced animals for human consumption.

The Federal Government could also commission another Expert Panel with a focus on biotechnology-produced animals. The resulting report could be compared to the Royal Society of Canada's Expert Panel Report on the Future of Food Biotechnology (2001). In addition, the Federal Government could also invest in independent scientific research and set up a system of third-party verification.

The CFIA's website states "Confidential business information is considered valuable to the companies that provide it for assessments, and the Government is required by law to assure that such information is not given to unauthorized recipients" (CFIA, 2012g). Companies and regulators, however, could agree on a third party, external and independent to the Federal Government and industry, to conduct an independent scientific review of the data submitted to Health Canada or Environment Canada concerning biotechnology-produced animals. Confidentiality agreements could be used to make this happen.

An independent review could examine company claims about their products. A Green Party member said "If these products are really as good as the companies say they need to prove that to the public. If a company is going to make a claim that they are producing a drought tolerant crop, well let's do some real science about this before they can make that claim" (GP-1).

Potential Role of Ministers and Members of Parliament

Former leader of the Green Party of PEI Labchuk saw the potential from increased awareness of widespread public interest in the issue among candidates and sitting Federal and provincial politicians who could make it an election issue (GPPEI). They could campaign to increase transparency and accountability in regulations and policies for the human consumption of biotechnology-produced animals through private member bills, question periods, motions, and educational outreach as well as by networking with NGOs including CBAN and the National Farmers Union.

Public Servants as Communication Providers

Public servants could “push from the bottom up”. Public Servants interviewed by the researcher provided examples of where they had fostered transparency regarding GE animals and biotechnology, including posting a risk assessment summary for the Enviropig online (as discussed in chapter 4.2.1). Committees and departments have also taken the initiative to hold meetings to inform people about what is going on and to explain legislation (OPP-2; PS-1).

6.3. *Opportunities for Interested Stakeholders outside of Federal Government to engage in and/or assess Policy and Decision-Making Processes*

It's up to citizens if this is going to be stopped, there has to be a groundswell against it (NGO-2)

In this thesis, primary and secondary research uncovered many possible opportunities for interested stakeholders outside of Federal Government to engage in and/or assess policy and decision-making processes in order to foster transparency and accountability in Federal policies and regulations with respect to the human consumption of biotechnology-produced animals. A number of activist strategies were suggested including making the question of biotechnology-produced food one that mattered in an election, to pressure politics.

An NGO representative said that food must become an election issue and be part of the candidates' platforms. The representative said all members of Parliament should have an understanding and a position on food:

We need to make them accountable we need to make it an election issue. We need them to be scared that this is one of the things that is going to cost them the next election. That can only happen if we have a groundswell of people out there who are pushing back and saying no. It's not just about the actual issue about GE wheat or GE pigs. It's also about transparency. (NGO-3)

Interested parties could also pay closer attention to what is going on in the House of Commons and publicly support Private Member's Bills and Motions that promote transparency and accountability regarding policies and regulations for biotechnology-produced animals.

An MP from the opposition said that consumers need to demand the transparency they feel is necessary (OPP-2). A Liberal MP said that unless the court or the court of public opinion (media and what people are saying on the street) demands it the Federal Government will not be forthcoming. The MP said that when Canadians demand answers “the Government feels the

pressure coming from the public, but if the public doesn't do that then the Government goes, maybe we can sweep it under the carpet" (LMP-2). A participant said "It's as much your responsibility as it is mine. It is each of our responsibilities in whatever capacity that we are operating in at the time to get the word out and inform people" (OPP-2). A professor who is a specialist in the study of Canada's environmental risk assessment of GMO described pushing for labeling as the "tip of the iceberg" but a way to get people to rally around the issue (ACAD-1).

Public pressure could enhance the potential for interested parties to have an impact and a greater role in policy. CBAN's coordinator believes that there is a role for CBAN to play in policy, not because Federal Government is open to it, but because it is necessary and that public pressure could support that role (NGO-1). Public pressure that is focused on challenging the core of the system and expanding the perimeter of the scope of the policy could increase transparency and accountability in decision-making for biotechnology-produced animals.

One food policy consultant suggested regulatory changes might happen through applying constant pressure on the civil service to reveal that "the system and the people in it are incompetent and a political liability" (ACAD-2). The consultant suggested instead of going after the politicians, you go after the civil servants in a way that makes the politicians uncomfortable because they feel they have an incompetent civil service structure underneath them (ACAD-2). Interested stakeholders could also lend support to public servants who find themselves in the role of "whistle blowers" when it comes to this topic area.

A former executive director of the Canadian Institute for Environmental Law and Policy (CIELAP) argues that citizens should write to MPs, or to newspapers, and to educate the public. The former director also said that CIELAP had been successful in producing a citizens' guide to biotechnology and distributing it into schools (NGO-C). An MP said that if you want the Canadian public to understand what is going on you have to start writing letters to the editor about political matters. The MP thinks 10% of what he writes gets published (OPP-2).

The issue of biotechnology-produced animals provides a powerful draw for a variety of interested stakeholders who could join forces and share resources to push for increased transparency and accountability in regulations and policies. Campaigns could include farmers, academics, NGOs, food groups, school groups, hunger organizations, consumer groups, MPs, and industry representatives. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that it's really important to have your ear in the

farming community especially in those communities where these crops or animals are being developed (ACAD-1). An NGO representative said that the NFU sits on the CBAN steering committee and that NGOs have greater clout when they echo each other. She said “we’re also members of Food Secure Canada and Food Secure Canada also mirrors our position.” She said that it’s necessary to work with a national food organization such as Food Secure Canada, so that it’s more than just the farmers’ saying no “through pushing back at that level it’s going to become an election issue” (NGO-3). A food policy consultant provided an example of a successful public campaign with multiple stakeholders groups that had stopped Bovine Growth Hormone from being approved in Canada (ACAD-2).

Interested parties could also reach out to researchers and advocates internationally. An NGO representative connected with researchers and advocates in the United States and joined them on a four-day speaking tour through the Maritimes that discussed biotechnology-produced fish that he described as successful (NGO-2).

Members of the interested public could also reach out to industry groups and businesses that are involved with biotechnology-produced animals. An NGO representative notes that they had met with Ontario Pork and posed the question “why do this?” (NGO-3) A food policy consultant said

Sometimes we tend to think the business side is a bit monolithic on the stuff, that they are lined up with the state on how things should unfold but in fact in the agricultural system there are many different actors. The system is so complex you get all kinds of different opinions depending on who you’re talking to. (ACAD-2)

Grassroots campaigns are also effective in raising awareness about the need for increased transparency and accountability in regulations and policies for biotechnology-produced animals. Interested parties could start a grassroots campaign to talk about the issues related to biotechnology-produced animals, including those that are and those that are not being assessed through Federal Government regulations and policies. An NGO representative said that a grassroots approach is needed

We can hold [the Federal Government] accountable using facts and figures and hard data but they’ll choose to ignore it and that’s the frustrating part. We need to change our strategy to grassroots organizations... it used to be that we go straight to the top and lobby the top – now we need to go straight to the bottom and lobby the grassroots. (NGO-3)

A professor who is a specialist in the study of Canada's environmental risk assessment of GMO noted that there are additional issues such as ethical, animal welfare, and animal rights issues in terms of GE animals that are slightly different from issues concerned with GE crops. She said “a different kind of ethical issues related to animal engineering affect people in a different way” (ACAD-1). She recognized that the public could rally around the issues but pointed out that the problem with that is the public doesn't know the issues (ACAD-1). An NGO representative also said we're the ones who need to unpack it and let people know what's going on (NGO-3).

Interested parties could also work to create an alternative regulatory system and national food policy (as is done through People's Food Policy and the Conference Board of Canada). A food policy consultant said that the creation of a national food policy “is not going to come from inside the Government, it will come from the outside. We are going to have to work out all the details” (ACAD-2) and he said that there are “way more details than we've done right now which is the weakness of social movements. We do not have the capacity or the willingness to do the real tough slogging work which is to go deep into the system and to propose concurrently all the things that need to be changed” (ACAD-2).

Opportunities for Industry Transparency and Corporate Citizenship

The researchers and producers of biotechnology-produced animals could find it in their own enlightened self-interest to provide more information concerning their product(s) than the information provided by the Federal Government. A public dialogue can be created through a trusted independent third party discussing the benefits and risks of these products.

Opportunities at the Municipal Level

Decisions regarding GMOs can also be made at the municipal level. On May 29th 2012, the Council of Richmond City, British Columbia unanimously confirmed a decision to make the city a GE Free Zone. The city also agreed to send letters to all levels of government “requesting strengthened management of genetically modified plants, and including the introduction of mandatory labeling requirements, more transparent assessment procedures and enhanced communication with the public” (CBAN, 2012c). Other GE free zones in British Columbia include Powell River, Kaslo, Nelson, New Denver, and Rossland.

6.4. Additional Possible Approaches

Participants described many avenues to obtain information both within and outside of the Federal Government that could be used to shed light on Federal decision-making processes. Some of these have been described in previous chapters. Five that stood out were: looking at information that is fed into the decision-making; examining administrative structures; following funding; paying attention to what is going on in the international community; and obtaining information that is being released by Civil Servants.

Research the Information that Influences Decision-Making Regarding Animals Derived through Modern Biotechnology (Channels that flow into Cabinet)

A Liberal MP suggested looking into what information was fed into the decision-making process instead of just looking at the final decision. The MP said that the process around decision-making is very broad as it is usually done around the Cabinet table. The MP said that opening access to some of the channels that flow into the decision-making process, like departmental analysis and advice prior to decision-making, would allow better insight into why the decision was made. As the MP stated it provides insight into whether the department or the ministers listened to the advice of the Civil Servants and whether the advice of the Civil Servants is totally off the mark (LMP-2).

Examine Administrative Structures

The Federal Government Employee Directory found on the Federal Government of Canada website could be used as a source to see how departments are split and to determine the hierarchy of departments (NGO-1). Knowledge of how resources are allocated in Federal Government institutions and departments could also provide some insight into the ability of decision makers to complete their tasks.

Follow Funding

Another suggestion was that it was possible to “follow the money” from the sources to the recipients to find out what is being funded and what work on biotechnology-produced animals is

being done by whom. A professor who is a specialist in the study of Canada's environmental risk assessment of GMO said that although access to information is more difficult in the corporate world, sometimes company websites include information on current research. The scientist said that even though detailed information may not be available “it’s one little hint as to where you need to be digging.” She also suggested university collaborations as a potential source of information for what is being funded and what may be coming down the pipe line (ACAD-1). It’s just as important to look at funding cuts as a potential source for information on the direction Federal Government is taking regarding policy making. A Liberal MP said that the last budget included an intentional defunding of alternative voices, including those of the environmental movement (LMP-1).

Participate / Pay Attention to decisions being made in the International Community

Paying attention to what is going on in the international community can shed light on what applications will be submitted to Health Canada and Environment Canada concerning biotechnology-produced animals. An NGO representative who attended the United States of America’s Food and Drug Administration hearings on the AquaAdvantage™ salmon (as discussed in chapter 5.2.2) (NGO-2) learned that the AquaAdvantage® salmon application was based on growing the fish eggs in Canada in a commercial facility for which the company, AquaBounty Technologies, had not received approval. Monitoring the direction Canada’s trading partners are taking and actions the Federal Government is taking in the international community with respect to biotechnology-produced animals can also lead to valuable insights into issues of accountability concerning Federal Government policies.

Obtain information that is being released by Civil Servants

Despite the paucity of information on many issues, there are Federal Government outlets for information on GE Animals that could be accessed by the public such as the posting of summaries of risk assessments on Environment Canada’s website or on Novel Food on Health Canada’s website. An Environment Canada employee stated that although it could be a bit dry, all the information was laid out in legislation and in regulations and Environment Canada would make attempts to try and explain it to any interested parties (PS-1). An NDP MP said that

committees do good work but that the Canadian public has little idea about the number of studies and amount of information within these studies. He said that that reports are accessible but acknowledged that they can be challenging to go through (OPP-1).

6.5. *Why the Federal lack of Transparency around GMO Food Regulations?*

This research project has shown that there is a lack of transparency around GMO food regulations, something for which the current Government has been critiqued on multiple occasions (Berthiaume, 2012; Smith, 2012; LMP-1; NGO-3; NGO-C: ACAD-1). This thesis has also noted a lack of transparency behind GE food regulations and policies under previous governments. The political will to increase transparency regarding GMO regulations has not been present under previous governments and it does not appear that the current government has the political will to review issues of transparency that have arisen concerning GE foods, or to increase transparency (Wasylycia-Leis, 2001; Royal Society of Canada, 2001; Andree, 2006 p. 1; Andree & Sharratt 2004, p. 20; Schmidt, 2011c; NDP-J; NDP-A; GPPEI; NGO-1; NGO-3; NGO-C; ACAD-1; ACAD-2; JOUR). It is troublesome, but not surprising, that this trend for GMO food regulations continues under the current government.

Federal policies and regulations are based on the premise that GMOs are as safe as their natural counterparts. For example Health Canada uses the concept of substantial equivalence as a guide in the safety assessment of novel foods (Health Canada, 2006d). Federal policies and regulations view the process of using modern biotechnology techniques as not introducing new health and safety risks to the food system (Health Canada, 2006d; CBAN, 2012a). GMO food regulations also only assess science-based risks. Based on these assumptions there is no reason for the Government to hold consultations or discussions for GMO food regulations regarding risks that are not science-based, or as new biotechnology-produced food products, like biotechnology-produced animals, are being assessed for entry into the Canadian food system. Health Canada's website does states that studies to address long term health effects may be a valid approach "should developments in the technology result in modifications that provide significantly different nutrient combinations or other novel food characteristics not previously encountered in the food supply" (Health Canada, 2006d). The regulatory process is designed to address new risks, when appropriate, that arise from the use of biotechnology.

Roles and responsibilities for GMO regulations are also spread across Federal Departments and Agencies. Transparency issues can arise from the ability of the public to stay informed on the roles of each department and agency and when regulations are being updated.

It also may be challenging for the Federal Government to provide information to and hold discussions with a participatory public on a complex subject like GMO regulations. This is especially true as the focus of GMO regulations are limited to assessing science-based risks and do not take into consideration socio-economic, economic or ecological risks (ACAD-2; GEPEI). Those that can provide advice or join in consultations surrounding GMO regulations are limited to experts that understand the science behind biotechnology (NGO-1). The lack of transparency around risks that are not science-based exists in GMO regulations as the responsibility to assess these risks remain outside of GMO regulations.

A lack of information being released by the Government to a participatory public can lead to the creation of what members of the public consider ineffective policies. This is especially true in the case of GE foods as the policy framework has been critiqued for having been designed without a public debate (ACAC-2). As regulations and guidelines are continuously being updated and created it also might be challenging for regulatory bodies to keep the public informed. An example of this would be keeping websites and links to documents up-to-date.

The government also cannot release confidential business information submitted during the assessment process to approve biotechnology-produced animals for human consumption or environmental release (CFIA, 2012g; Royal Society of Canada, 2001 p. 213; Government of Canada, 2010 p. 90; Patterson, 2010; IND; NGO-1;; NGO-1; JOUR). The release of confidential patented company information could also negatively affect competitiveness. The Government also has an interest in accommodating business interests in a sector that is extremely capital intensive concerning product development (Royal Society of Canada, 2001; IND).

For this research project, the researcher also faced difficulties in presenting the Federal Government's side of the argument due to the very lack of transparency that appears to have prevailed throughout the current government's mandate. This made it difficult to get in contact with people who were willing to speak about the issue, would agree to be interviewed and release consent after the interviews took place.

6.6. Conclusion

Mechanisms are available for overcoming limitations to transparency laid out in the previous chapters surrounding the human consumption of biotechnology-produced animals. Some of the opportunities raised by participants also have the potential to foster food democracy. The Federal Government can still maintain confidentiality of businesses' proprietary information while opening up a dialogue with interested parties. Avenues for change for civil servants and elected officials exist through the Federal Government's release of information; the involvement of non-state actors through consultation processes and third-party verification; through ministers and members of parliament and through public servants being communication providers. Interested stakeholders outside of the Federal Government can lobby by making it an election issue, participating in grassroots campaigns, and for industry to foster transparency and corporate citizenship. Avenues also exist for citizens to act proactively through researching information that influences decision-making, examining administrative structures, following funding, paying attention to the international community, and through obtaining information that is being released by civil servants.

This might have to be the case if change is to happen in the immediate future for as discussed in Chapter 4, there is little indication that the government is motivated to foster transparency. At the time of writing, the current government has indicated that it is moving in the opposite direction. A Liberal MP believes that the current government (as of 2012) is possibly the least transparent government in the history of Canada (LMP-1). The MP said that information is power and in regards to the Conservatives, "are all about power and will only share information after virtually putting a proverbial parliamentary gun to their head" (LMP-1). An NGO representative stated "we need bad press for the government, to unpack the stuff and give them bad press because they're just doing all these things behind closed doors" (NGO-3). Former CBAC and CIELAP member Mitchell stated "We're in a stage with our Government that it doesn't matter what you say to whom, they're blinkered. They're going where they're going and how we change them apart from getting rid of them, I don't know" (NGO-C). A professor who is a specialist in the study of Canada's environmental risk assessment of GMO stated "They've really tightened the screw on information – it's not a good day for democracy. Transparency is definitely not at its highest at the moment – not that it's ever been very good but it's getting worse" (ACAD-1).

Chapter 7 Summary, Conclusions and Recommendations

7.1. Summary

This research paper examines the transparency of the Federal Government's decision-making processes and institutions with respect to the human consumption of biotechnology-produced animals. It identifies current issues in order to assess and analyze the transparency of the Federal Government's decision-making processes and institutions as well as challenges and opportunities for increasing transparency before regulations are finalized. It provides a timely study for, at time of writing, the Federal Government is currently deciding whether and how biotechnology-produced animals are to be approved for human consumption. At this time, the Federal Government was also assessing a notification to approve a biotechnology-produced animal, the Enviropig™ for human consumption. Government decisions regarding the human consumption of biotechnology-produced animals in the following years have the potential to revolutionize food systems on the national and international level.

A historical analysis reveals an enduring lack of transparency and accountability regarding the Federal Government's decision-making processes and institutions for foods derived through modern biotechnology which has continued to the present day throughout both Conservative and Liberal governing mandates. These limitations are still present for the regulation of biotechnology-produced animals. Current issues with biotechnology-produced animals outline the decreasing transparency and accountability of the Federal Government with regards to GMO regulations. This research project concludes that there is little indication that the Federal Government is motivated to foster transparency.

7.2. Discoveries

Seven themes concerning the transparency and accountability of federal decision-making processes and institutions with respect to biotechnology-produced animals were identified through interviews with key stakeholders. A majority of participants discussed the lack of publically-available information. Most participants pointed out inadequacies in the current policy and regulatory framework and suggested that there is a lack of political will to ensure transparency. Just over half of interviewees hypothesized that this could be due to the Federal Government's biased agenda towards biotechnology and that transparency appeared to be a

growing problem due to declining avenues for public participation and reduced consultative initiatives. A few stated that transparency appeared to be a growing problem due to a disempowered Parliament and a decline in public servant interactions and communications flow.

Through an interpretive qualitative analysis of primary and secondary data these themes were compared with limitations to transparency found in the literature. The research project identified limitations that stem from the confidential nature of the regulatory processes, how and what risks are assessed during the assessment processes and the independence, objectiveness and quality of the science used in the assessment processes. Limitations also stem from the private-sector framing of regulations, the ability to “let the market decide” and the lack of a unique policy framework and division of regulatory responsibility.

The research project identified existing and potential opportunities to increase transparency. The Federal Government can maintain private sector competitive interests while still opening up a dialogue with interested parties. This can be fostered through the Government’s release of information, the involvement of non-state actors in consultative processes and the use of a third party, like the Royal Society of Canada, to verify Government data and to review the policy direction for GMO food regulations. Ministers and Members of Parliament could also campaign to increase transparency and accountability in regulations and policies. Public servants could also re-examine their role as communication providers.

Opportunities for increasing transparency regarding the research topic also exist for interested stakeholders outside of the Federal Government. These stakeholders could focus on making the subject an election issue and through participating in grassroots campaigns at all levels including the municipal level and the international community. Stakeholders who are researching and producing biotechnology-produced animals also have the opportunity to foster transparency and corporate citizenship, especially through opening a public dialogue through a trusted third party to discuss the benefits and risks of consuming biotechnology-produced animals. They can also research the information that influences government decision-making; administrative structures; funding; information released by civil servants, the media and members of academia; and pay close attention to what the Canadian Government is doing in the International community. Such knowledge is a crucial first step to the identification of the important pressure points for change.

The researcher found that attempts by the Federal Government to increase transparency through the use of Acts and food safety initiatives have little impact on a policy process that is based on confidentiality. Food safety initiatives have not been extended to examine any new risks to consuming food products that can be introduced by the process of using modern biotechnology to create biotechnology-produced animals. Federal attempts such as Acts to foster sustainable development in departments are limited by the definition of sustainable development used by individual departments.

There is a lack of citizen engagement and consultation in the creation of the regulatory process for biotechnology-produced animals. Working groups and advisory bodies exist concerning food safety but the transparency and accountability of the research topic is more than an issue of the Federal Government setting up advisory bodies to obtain advice from select stakeholders. The majority of the population, even with these bodies, still does not have access to information regarding the decision-making process and what is going on and are not being consulted.

7.3. *Recommendations*

Without a solid understanding of public perception and acceptance of these animals into the food system, it is difficult to tell how much transparency is needed or wanted in the regulatory process. Polls and surveys have identified that there is low public acceptance in both Canada's regulatory process for biotechnology-produced animals as well as the introduction of biotechnology-produced animals into the food system. The researcher found that there is no indication public confidence will be increased with the introduction of more biotech products. This is especially true given that the Federal Government is not conducting long term studies and the independent studies have raised issues of confidence concerning the regulatory system. Products that fall under GMO food regulations are also becoming arguably more complex with expanding risk bases. Public engagement and consultation is needed before moving forward with these technologies. For example, there is a need for public consultation and engagement to determine if and how potential broader impacts beyond science-based risks of approving these products are to be taken into account (i.e. to assess the potential for the closure of export markets).

On that note, Canadians have to work for transparency if they want it. Interested stakeholders can connect and seek out the transparency and accountability they think is necessary in decision-making for biotechnology-produced animals. While it is not feasible for the Federal Government to “spoon feed” the information to the public, the information should be made available for those who are seeking it. This goes beyond making information available through right to know legislation or voluntary initiatives. It is understandable that confidentiality is needed, but it is also clear that there is a need to be transparent about how regulatory bodies are ensuring the protection of the food system. Moreover, if the government objective is to promote commercial interests, a regulatory process can also negatively affect business if there is no trust or accountability in the process or product that is being or has been reviewed.

Transparency is centered on information that is released by the Government regarding GMO food regulations and applications. There is a lack of information regarding the human consumption of biotechnology-produced animals being proactively released by the Federal Government on what it is working on, on regulatory processes, on issues it has to face, and on applications that have been submitted or are going through the regulatory process. The information that gets released by the government is fractured and is intermittent. Regulatory departments have been working on regulations and policies to assess biotechnology-produced animals for human consumption for over a decade. How a biotechnology-produced animal would be assessed for human consumption is unknown as regulations are currently being updated. As discussed in this paper, regulations are being updated in a piece-meal approach, and the approval of biotechnology-produced animals for specific commercial purposes does not happen concurrently. There is a need for the Government to release information concerning how it will regulate the human consumption of biotechnology-produced animals, as well as GMO food regulations in general.

The information that is released by the Federal Government is limited by the confidential nature of the regulatory processes. Interested parties must rely on information provided by voluntary initiatives undertaken by departments, or by the applicant. For example information that has been provided by the University of Guelph regarding the Enviropig™ application for human consumption was provided on a voluntary basis by the University. The Federal Government has nothing set up to provide information on applications that it has received or is working on concerning the human consumption of biotechnology-produced animals.

It should not be considered acceptable to leave it up to employees of Federal departments to go outside of their mandates to fill in transparency voids of the overall policy structure, or for the applicant to bear the brunt of questions concerning its application. In the case of biotechnology-produced animals transparency is even more elusive because even the limited transparency initiatives that have been set up for Plants with Novel Traits do not apply to biotechnology-produced animals. Transparency initiatives need to be set up for biotechnology-produced animals to at least be equivalent to the information being released regarding PNTs. At the very least, transparency surrounding GMO regulations and applications can be increased through the Federal Government updating websites, checking for accuracy and biases, and fixing broken links to relevant documents. The researcher would like to acknowledge her use of web archival sites, like *Wayback Machine*, to obtain information that had been taken down from Government websites.

Breaking down the barriers identified in Chapters 4 and 5 and fostering the opportunities discussed in Chapter 6 can aid in incorporating food democracy into Canada's food system and in increasing democratic participation.

The timeline given in Appendix A can aid in creating a living document that records the history of decision making surrounding GMO food regulations. It can also be utilized to aid in comparing when GE foods have been brought up in the media or through the House of Commons to Federal Government responses (i.e. through food safety initiatives).

Federal government approaches to transparency, even when applying the very limited formal institutional notion is a long way from being realized, particularly with respect to genetically engineered foods. This is a concern given that the definition, understanding, and implementation of transparency need to be expanded in the context of food democracy. In fact, it can be argued that since 2006 with the election of the Conservative government, there has been a loss of capacity to ensure transparency. As discussed in this thesis, that loss has included concerns about a decreasing ability for private and public actors to gather information from governing bodies, conduct research on genetically modified organisms, and participate in consultative initiatives. Concerns about the loss of capacity can be seen in issues raised in this research paper including the inability of stakeholders to effectively utilize the Access to Information Act, the lack of publically accessible information since 2006 on how regulations are being updated to incorporate the human consumption of animals produced through

biotechnology, the lack of a public review of the regulatory, policy framework, identified issues concerning transparency, a paucity of information posted on government websites specifically with respect to decision documents, and the apparently limited amount of research being completed by the government, especially in the area of long-term testing and traceability. This apparent loss of capacity adversely affects the ability of Canadian citizens and residents to have any input into issues the most directly affect them—namely how their food is regulated and handled. As such, they have limited means to ensure the safety of their food system. This identified loss of capacity and the formal institutional notion of transparency raise issues of public democracy and governance with respect to many issues including the potential human consumption of animals produced through biotechnology. The latter is a timely concern, for this issue needs to be addressed before animals produced through biotechnology are approved and introduced into the food system, nationally and globally.

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Appendix A: A Timeline of Events Regarding Genetically Engineered Foods

Events that take place within the same month might not be in chronological order. When specific dates are given they are provided in brackets (i.e. (Aug 5)). The events where only the year was given are listed directly under the heading for that year.

Events that are highlighted are not directly discussed in the body of this research paper.

~ Mid 1980s ~	
Mid 1980s	Increasing amounts of products derived through rDNA techniques are nearing the stage of commercialization.
Mid 1980s	Regulatory authority over biotechnology products is given to existing departments that held authority over the same products made from traditional techniques (Moore 2000, p. 96).
~ 1983 ~	
1983	Release of Canada's National Biotechnology Strategy (NBS). Establishment of Canada's National Biotechnology Advisory Committee (NBAC).
~ 1987 ~	
1987	Regulatory departments agree to build on existing legislation and internationally developed guidelines, to regulate the product and not the process of genetic engineering, and to use risk based assessments (Kneen, 1999 p. 135).
~ 1992 ~	
Aug. 1992	(Aug 5) Health Canada releases Information Letter (IL) No. 806 to interested parties. The letter describes Health Canada's proposed approach to assess the safety of novel foods and was released so interested parties could comment on the proposed approach. This Information Letter was the Canadian government's first public step in the development of safety regulations for novel foods (Health Canada, 2000).
~ 1993 ~	
Jan. 1993	The Government announces a new Federal Regulatory Framework for the regulation of biotechnology products. A key principle was to continue using existing laws and regulatory departments to ensure that "the benefits of biotechnology products and processes are realized in a way that protects health, safety, and the environment" (Health Canada, 2012d).

Nov. 1993	Agriculture Canada, Health Canada, Environment Canada and Industry and Science Canada conduct the consultation workshop <i>Regulating Agricultural Products of Biotechnology</i> . The need for further public consultations is evident (Moore 2000, p. 197).
~ 1994 ~	
1994	A poll commissioned by Industry Canada shows that up to 95% of Canadian consumers want labels on GE Foods (Council of Canadians, 1999).
Sept. 1994	Health Canada's Health Protection Branch release <i>Guidelines for the Safety Assessment of Novel Foods, Volume II: Genetically Modified Microorganisms and Plants</i> to assist developers in their product safety assessments. It was up to the developer to determine whether review by Health Canada was advisable (Moore 2000, p. 146). The guidelines refer to GE food as novel foods, and GE plants as Plants with Novel Traits (PNTs) (Food Directorate Health Protection Branch, 1994).
Nov. 1994	A multi-stakeholder <i>Technical Workshop on the Labeling of Novel Foods Derived Through Genetic Engineering</i> is held to produce consensus on general principles and was attended by approximately 60 participants. The workshop serves as the basis for the development of Canada's regulations for GE foods (Moore, 2000; Kneen, 2000).
~ 1995 ~	
Aug. 1995	<p>Health Canada proposes the establishment of a new division in the <i>Food and Drug Regulation</i> in the Canadian Gazette I "that will define the concept of a novel food and provide for notification prior to the sale or advertising the sale of such food products" (Health Canada, 1995 p. 2987). Thirty five responses were received that commented on the proposed amendments (Health Canada, 1995). Of responses, "28 were on behalf of industry or industry associations, 2 were from agencies of one foreign government, 2 from individual citizens, 1 from a labour organization, 1 from an environmental interest group and 1 from a consumers group" (Regulations Amending the Food and Drug Regulations, 1999). Health Canada published the revised version of its proposed new regulations in September 1998.</p> <p>Health Canada's Regulatory Impact Analysis Statement considered two options: the premarket approval similar to that required for food additives; and the proposed pre-market notification option. The pre-market approval approach "was viewed as introducing unnecessary impediments to the marketing of novel foods without providing a corresponding increase in the level of consumer protection" (p. 2989). The Regulatory Impact Analysis Statement states that regulatory principles it described were supported by responses to consultations that had taken place and that the issue of labeling GE foods remained to be resolved (p. 2989). The consultations listed in the Regulatory Impact Analysis Statement included Information Letter No. 806 (1992), the publication of the <i>Guidelines for the Safety</i></p>

	<p><i>Assessment of Novel Foods</i> and a public workshop the department co-sponsored with Agriculture and Agri-Foods Canada and the Department of the Environment concerning the regulation of agricultural products of biotechnology.</p>
Dec. 1995	<p>The AAFC release its <i>Communiqué: labeling of novel foods derived through genetic engineering</i>. The Communiqué compiled comments that had been made during the 1994 consultations. The <i>Communiqué</i> stated that participants of the Technical Workshop had reached a consensus that labels on foods that have been genetically engineered must identify potential health and/or safety risks for individuals, and/or significant compositional or nutritional changes (Food Inspection Directorate, 1995).</p>
<p>~ 1996 ~</p>	
1996	<p>The CFIA approves the “CDC Triffid” GM flax for environmental release. This flax lead to Europe closing its door on Canadian flax in 2009 (CBAN, 2012b).</p> <p>Health Canada’s Health Protection Branch publishes a revised version of its proposed new regulations for the safety assessment of novel foods under the <i>Food and Drugs Act</i>.</p>
May 1996	<p>The Standing Committee of the Environment discusses the regulatory framework for biotechnology. The topic was discussed over the course of the nine public hearings in May and June of 1996.</p>
Nov. 1996	<p>The Standing Committee on Environment and Sustainable Development came out with the report <i>Biotechnology Regulation in Canada: A Matter of Public Confidence</i>. The report states that Fisheries and Oceans Canada's regulations for GE fish are being drafted (Commissioner of the Environment and Sustainable Development, 2004b).</p>
<p>~ 1997 ~</p>	
Apr. 1997	<p>Establishment of the Canadian Food Inspection Agency (CFIA). The CFIA is given authority over novel feeds and genetically modified crop plants (Health Canada, 2012d).</p> <p>Agriculture and Agri-Foods Canada issue the Information Letter Communiqué: labeling of novel foods derived through genetic engineering. The Letter presents guidelines which form the basis for Canada’s labeling policy in regards to GE foods. The Information Letter summarizes comments that were made concerning the guidelines that were developed through the 1994 Technical Workshop on the Labeling of Novel Foods Derived Through Genetic Engineering Workshop. It also summarizes comments that were made on the AAFCs 1995 communiqué (Moore, 2000, p. 155, 197).</p> <p>The Department of Fisheries and Oceans Canada state in an internal memo that it is</p>

	“committed to having the regulations in place that year” (Commissioner of the Environment and Sustainable Development, 2004b).
~ 1998 ~	
1998	Health Canada approves the “CDC Triffid” GM flax for human consumption. This flax lead to Europe closing its door on Canadian flax in 2009 flax (CBAN, 2012b). (1998-1999) “Industry Canada's BRAVO Web site (as of 17 May 2004) states that GE fish regulations are expected to come into effect during 1998–99” (Commissioner of the Environment and Sustainable Development, 2004b).
May 1998	The House of Commons Committee on Agricultural report <i>Capturing the Advantage: Agriculture biotechnology in the new millennium</i> (Canada. Standing Committee on Agriculture and Agri-Food, 1998).
Aug. 1998	The renewed Canadian Biotechnology Strategy (CBS) is released to replace the 1983 National Biotechnology Strategy. No changes were made to the regulatory framework or principles. An emphasis was placed on strengthening interdepartmental coordination as well as public awareness and participation (Moore 2000, p. 117). The Canadian Biotech Advisory Council (CBAC) were created through the CBS to “provide expert advice to the Federal Government on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology” (Health Canada, 2006d). The CBAC was given a wider mandate than the NBAC (1983), which it replaced.
Sept. 1998	Health Canada’s Health Protection Branch publishes a revised version of its proposed new regulations for the safety assessment of novel foods under the <i>Food and Drugs Act</i> in the Canadian Gazette I with a comment period of 60 days through which nine comments were received.
Nov. 1998	(Nov 2-3) Multi-stakeholder consultation on "Regulating Livestock Animals and Fish Derived from Biotechnology". The consultations are sponsored and supported by Health Canada, the CFIA, AAFC, and the Department of Fisheries and Oceans.
~ 1999 ~	
Apr. 1999	Agricultural Minister Lyle Vanclief holds a closed door <i>Roundtable in Communications and Agricultural Biotechnology</i> with representatives of the biotech industry regarding the future of the biotechnology industry.
June 1999	A Prairie Research Associates poll shows 92% of Manitobans want labeling (77% of those polled believed GE foods were unsafe or were unsure of their safety) (Council of Canadians, 2011).

Sept. 1999	The Canadian General Standards Board (CGSB) and the Canadian Council of Grocery Distributors (CCGD) establish a multi-stakeholder committee to undertake the development of a voluntary labeling standard for foods derived from biotechnology.
Oct. 1999	An insert considered to critics as being pro-biotech appears in Canadian Living Magazine entitled <i>What Am I Eating? Consumers, Producers and Genetically Modified Foods</i> . The insert was sponsored by the CFIA (CFIA, 2000, p. 241). In a reference to the October 1999 insert, the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology reported "CFIA has engaged in active media campaigns promoting agricultural biotechnology, and seeking to allay public fears about risks associated with GM foods" (Royal Society of Canada, 2001, p. 212). (Oct 27) Health Canada publishes its final version of its Novel Food Regulations in the Canada Gazette.
Nov. 1999	An eight page pro-biotech supplement entitled <i>A Growing Appetite for Information</i> is featured in Canadian Living Magazine. The insert was funded by the CFIA. The insert did not acknowledge its connection with the CFIA. Bradford Duplisea from the Canadian Health Coalition discovered that the publications had been financed and edited by the CFIA through Access to Information requests. Duplisea questioned "Why didn't the CFIA just do these in-house... Why did they go through such elaborate measures to put these items out as if the CFIA is not associated with them?" (Steward, 2001).
Nov. 1999	(Nov 27) CIELAP release their report <i>The Regulation of Agricultural Biotechnology in Canada</i> . The report criticized the contradictory role of Canada's regulatory approach and was a comprehensive inventory of the gaps within the Canadian biotechnology regulatory frame.
Dec. 1999	A Montreal Gazette poll of 966 Montrealers found almost unanimous support for a mandatory GE food label. Over 50% of the respondents thought that GE foods should be banned (Abley, 2000). Establishment of the Royal Society of Canada's <i>Expert Panel on the Future of Food Biotechnology</i> at the request of Health Canada, the CFIA and Environment Canada.
~ 2000 ~	
Late 2000/early 2001	Fisheries and Oceans Canada's senior management commit to Environment Canada that regulations for GE fish will be in force in the fall of 2002 (Commissioner of the Environment and Sustainable Development, 2004b).
Jan. 2000	GE Alert, a group of scientists and academics, release the report <i>Food Safety of GM Crops in Canada: Toxicity and Allergenicity</i> . Findings reveal that testing of the toxicity and allergenicity of GE crops by Health Canada had not been

	conducted on 70% of the 42 GE crops Health Canada approved (McKenzie, 2002, p. 170). Dr E. Ann Clark, a Professor at the University of Guelph and member of GE Alert said that “Allergenicity was not assessed through lab or feeding trial measurements on any of the 42 GE crops. All conclusions of safety regarding toxicity and from allergenic responses were based entirely on inferences and assumptions” (Council of Canadians, 2000).
Mar. 2000	The CFIA publishes its controversial <i>Food Safety and You</i> pamphlet seen as being biased by those who questioned the regulatory regime and standard’s project. The pamphlet is mailed to Canadian households. The CFIA did state that the publication cost \$2.53 million (23 cents x 11 million copies) (Kneen, 2000).
Apr. 2000	Canadian researcher Brewster Kneen, a member of the consultation workshop held in November of 1993, raises concern about transparency of the formation of Canada’s regulatory process. Kneen utilizes the April 2000 edition of his newsletter, “The Ram’s Horn”, to outline his participation in the 1993 and 1994 public consultation workshops (Kneen,, 2000). Contrary to what was written in Agriculture and Agri-Food Canada’s (AAFC) <i>Communiqué: labeling of novel foods derived through genetic engineering</i> (1995) and a 1997 information letter of the same name, Kneen said that neither of the public consultations had reached a consensus on the topic of GE food labeling(Kneen, 2000). Kneen outlined multiple occasions where his involvement in the 1993 and 1994 consultations had been used by “industry flacks” to legitimize the consultative process. Kneen was referenced in a fall 1999 conference at McMaster University by Mary Lou Garr of AGCare, a February 2000 meeting in Saskatoon by Dale Adolph of the Canola Council, and a March meeting in British Columbia by CFIA’s Stephen Yarrow (Kneen, 2000).
May 2000	Fisheries and Oceans Canada states in its response to Petition No. 23, that it is developing regulations for GE fish (Commissioner of the Environment and Sustainable Development, 2004b).
May 2000	Petition No: 23 <i>Federal laws, regulations, and policies on genetically modified organisms (GMOs)</i> is filed under the Auditor General Act against the Federal Government for failing to protect public health and the environment in regulating genetically modified organisms.
~ 2001 ~	
2001	Health Canada releases a decision document that approves Monsanto’s GM corn NK603 for human consumption. This corn was used in a 2012 peer-reviewed study by the French group of Gilles-Eric Seralini that described harmful effects on rats fed on diets containing GE maize (Seralini, et al., 2012). The CFIA deregisters the “CDC Triffid” GM flax, making it illegal to sell the seeds (CBAN, 2012b). This was done at the request of the Flax Council of Canada and Saskatchewan Flax Development Commission over concerns about losing the European market (CBAN, 2012b). This flax lead to Europe closing its door on

	Canadian flax in 2009 flax (CBAN, 2012b).
Feb. 2001	<p>The Royal Society of Canada’s (RSC) Expert Panel on Biotechnology release their report <i>Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada</i> The Expert Panel uses the report to raise alarm about the ethics and safety of the use of GE crops and the potential risks posed to human health, biodiversity and the environment</p> <p>Dr. Brian Ellis (then Associate Director of University of British Columbia's Biotechnology Laboratory, joint head of the Royal Society of Canada Scientific Panel on Food Biotechnology, and Co-Chair of the Expert Report) states on the CBC radio program Quirks & Quarks the “issue is not with methodology itself but the secrecy that surrounds it” (McDonald, 2001).</p> <p>The Canadian Government responses to the RSC report through an Action Plan.</p> <p>(Feb 28) MP Charles Caccia (Liberal - Davenport Ontario), introduces private members bill, Bill C-287 to amend the <i>Food and Drugs Act</i> and make mandatory labeling standard for GE foods containing more than 1% GE ingredients and carry out studies on the long-term effects of GE foods on human health.</p>
Apr. 2001	<p>The Release of the Canadian General Standard Board (CGSB) Committee’s <i>Regulation of Genetically Modified Food</i> Consultation Document. Fifty Canadian NGOs declined to participate in the CGSB consultations. The document was used to solicit input from Canadians for the CGSB workshops on the Voluntary labeling standard (Council of Canadians, 2002).</p> <p>Sixty-one “civil society” groups sent letters to the Prime Minister’s Office boycotting CBAC and describing it as being fundamentally flawed (Glover et al, 2003).</p>
May 2001	<p>Wasylycia-Leis, NDP MP for Winnipeg North Centre and a member of the Health Committee, introduced Bill C-310 for the mandatory labeling of GE foods into the House of Commons.</p> <p>A Pollara & Earncliffe Research and Communications poll for the Globe and Mail shows that 94% of Canadians believed the government should order companies to label GM foods (MacKinnon, 2001).</p>
May 2001	<p>Debate on Bill C-287 was initiated by MP Charles Caccia in the House of Commons.</p> <p>(May 18) The CFIA sends a letter to several members of Parliament including Allan Rock, Lyle Vancleif, Brian Tobin, Minister of Industry, Pierre Pettigrew, Minister of International Trade, and Charles Caccia, expressing the view that the bill C-287 was unworkable (CFIA, 2001b).</p>

June 2001	(June 6) Debate on Bill C-287 is initiated by MP Charles Caccia in the House of Commons.
Aug. 2001	(Aug 22) CBAN releases <i>Improving the regulation of genetically modified foods and other novel foods in Canada: interim report to the Government of Canada Biotechnology Ministerial Coordinating Committee</i> .
Sept. 2001	<p>The Minister of Health announces that substances in products regulated under the <i>Food and Drugs Act</i> would be subject to the <i>New Substance Notification Requirements</i> (NSNR) under CEPA 1999.</p> <p>Health Canada publishes a Notice of Intent in <i>Canada Gazette</i> Part I to inform the public of the department's intention to undertake the development of appropriate Environmental Assessment Regulations (EARs) for new substances in products regulated under the <i>Food and Drugs Act</i> (Health Canada, 2010b). The EARs "will differ from existing requirements with respect to when companies are required to submit data and the type of data companies are required to submit" (Health Canada, 2011c). When finished the EARs would be published in the Canadian Gazette and would undergo a comment period before appearing in the Canadian Gazette 2. The objective of the new EARs is to ensure that those substances are evaluated for their potential risks to the Canadian environment and human health through environmental exposure (Health Canada, 2011c).</p> <p>Establishment of the Environmental Impact Initiative (EII) Division of Health Canada following the publication of a Notice of Intent in the <i>Canada Gazette</i> Part I.</p> <p>(Sept 1 – Oct 30) Opportunity to comment on Health Canada's Notice of Intent to undertake the development of EARs for new substances in products regulated under the Food and Drugs Act.</p> <p>(Sept 24) Wasylycia-Leis, NDP MP for Winnipeg North Centre and a member of the Health Committee, writes a policy briefing entitled "Government's Biotech Strategy Supports Biotech Corporations" that appears in <i>The Hills</i> September 24th, 2001 issue. She stated that voluntary standards were irrelevant to a public that consistently registers more than ninety percent support for a mandatory label (Waylycia-Leis, 2001). She refers to an open letter that had come from a "broad coalition of more than 200 consumer, environmental, and farm producer groups concerned for the future of Canada's \$6 billion per year overseas wheat sales." She states that the Government had chosen not to act on any of the Royal Society of Canada's suggestions declaring that it would prefer to wait until the CBAC and CCGD had finished their reports (Waylycia-Leis, 2001).</p>
Oct. 2001	(Oct 12) A letter is sent to the Chair of the Standing Committee on Health that spoke out against Bill C-287 and suggested the Committee hold hearings about the best options for meeting consumers' information needs with respect to genetically modified foods. The letter was signed by the Ministers of Health (Allan Rock),

	<p>Agriculture (Lyle Vanclief), Industry (Brian Tobin) and International Trade (Pierre Pettigrew) (Freeman, 2001). The use of the Standing Committee was described in the media as an attempt at a stalling technique as well as a way to take focus away from Bill C-287.</p> <p>(Oct 17) When Liberal MPs showed up to the House of Commons to vote on Bill C-287 they found a pamphlet entitled, “vote against bill C-287 and support Canada’s agri-food business” on each of their desks (Freeman, 2001).</p> <p>(Oct 17) Bill C-287 is defeated 129 to 91 in the House of Commons. Health Minister Allan Rock, the only senior Cabinet Minister on record as supporting mandatory labeling, avoided the vote out of cabinet solidarity (CBC, 2001).</p> <p>(Oct 23) The Standing Committee on Health releases a statement that they have adopted the proposal to study the issue of GE food labeling.</p>
Nov. 2001	<p>The Federal Government responds to Royal Society Paper through an Action Plan</p> <p>Greenpeace submits Petition 38A on Genetically Engineered Fish to request “information about Federal Government policy concerning the rearing of genetically engineered (GE) fish. Greenpeace maintains that all GE fish should be raised in secure, land-based facilities as the risks associated with rearing GE fish in open net pens in oceans and lakes are too high” (Office of the Auditor General of Canada, 2001).</p> <p>“A senior management briefing note states that the Minister of Fisheries and Oceans committed to developing the regulations by the fall of 2002.” (Commissioner of the Environment and Sustainable Development, 2004b).</p>
~ 2002 ~	
2002	<p>The University of Guelph send eleven Enviropig™ piglets to a rendering plant where they were unintentionally turned into animal feed. Egg farmers, turkey farmers, and broiler chicken producers in Ontario were sold 675 tons of contaminated poultry feed (Strass, 2002). The animals were supposed to have been destroyed as biological waste. The bodies of these piglets were being “stored in a refrigerator at the University's Ridgetown research station with bodies of animals meant to be sent to the renderers and were accidentally taken away with them” (Strass, 2002).</p> <p>A Pew Global Attitudes Project survey reports that 37% of Canadians viewed scientifically altered fruits and vegetables as good, whereas 63% thought these products were bad (Martin and Grey, 2010).</p> <p>The Public Advisory Committee (PAC) forms to advice Health Canada's Health Products and Food Branch (HPFB).</p>

	Lucy Sharratt from CBAN writes the report <i>Regulating Genetic Engineering... for Profit</i> through the Polaris Institute
Jan. 2002	The Canadian government release a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports
Jan. 2002	CIELAP submitted to the CBAC <i>Comments on the Interim Report "Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada"</i> (Jan 18) Greenpeace submits <i>Petition 44 Post approval monitoring of genetically modified organisms (GMOs)</i>
Jan - Apr, 2002	The Standing Committee on Health study is initiated in January of 2002. Four public hearings are held between January and Apr, 2002 During the hearings Greenpeace Canada and the Canadian Health Coalition (CHC) release documents that suggested "the Federal Government has spent \$3.3 million in to promote the safety of GE Foods" (Greenpeace, 2002; Wilson, 2002). Officials challenged the numbers and stated they were not promoting biotechnology. During the same hearing Wasylycia-Leis, NDP MP for Winnipeg North Centre and a member of the Health Committee, asked "aren't you running the risk of being seen as the mouthpiece of the biotech industry?" (Wilson, 2002) Suzanne Trembley, a Bloc Quebecois MP also raised that issue (Wilson, 2002). The Royal Society's Expert Panel on the Future of Food Biotechnology co-chairs Brian Ellis and Conrad Brunk also used the hearings to reiterate the Expert Panel's recommendations. During the hearings CBACs Co-Chair Peter Phillips stated mandatory labeling could cause a North American Free Trade Agreement trade war: "It would undoubtedly complicate our relations with our major trading partner, the United States, and complicate the access of our market into their market and vice-versa" (Stewart, 2002).
Mar. 2002	The Canadian Institute for Environmental Law and Policy (CIELAP) releases its <i>Citizens Guide to Biotechnology</i> . CIELAP stated its guide was "not a traditionally balanced approach, but we take it because the critical perspective provided here is largely absent from the information provided to citizens by the federal government and the biotechnology industry." (CIELAP, 2002, p.2).
Apr. 2002	Health Canada and Environment Canada sign an MOU regarding the NSNR, giving Health Canada responsibility over the NSNR assessments for products in the <i>Food and Drugs Act</i> . The HPFB release a <i>Technical Discussion Report</i> in response to the Royal Society of Canada Expert Panel Report. Fisheries and Oceans Canada states in its response to Petition No. 38A that it is developing regulations for GE fish. (Commissioner of the Environment and Sustainable Development, 2004b).

May 2002	The Canadian government release a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports
May 2002	Canadian researcher Devlin Kuyek publishes <i>The Real Board of Directors: The Construction of Biotechnology Policy in Canada, 1980-2002</i>
June 2002	The Standing Committee on Health completes its study <i>Labeling of genetically modified foods and its impact on farmers</i> (Canada. Standing Committee on Agriculture and Agri-Foods, 2002).
Aug. 2002	<p>Health Canada releases a draft of its <i>Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms</i></p> <p>(Aug 26) The CBAC released its final report entitled <i>Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada</i>. The CBAC promoted it as a “comprehensive and balanced report which identifies opportunities for improvement of the Government regulatory approach for products derived through biotechnology” (Health Canada, 2006d). CIELAP Executive Director Anne Mitchell, one of the twenty- committee members was “strongly in favour of proceeding directly to mandatory labeling” and had noted “a majority of respondents to our Interim Report urged a mandatory system” (CBAC, 2002, p. xi).</p> <p>Nadège Adam, campaigner for the Council of Canadians, stated</p> <p>CBAC's credibility is and will always be an issue given its membership composition...The vast majority of the committee members have either ties or notable sympathies towards the biotech industry. It comes as no surprise that the basic concerns of Canadians are not reflected in this report. (Council of Canadians, 2002)</p> <p>The CBAC reports that Fisheries and Oceans Canada is currently developing regulations for GE fish (Commissioner of the Environment and Sustainable Development, 2004b).</p>
Aug. 2002	The U.S. National Academy of Sciences releases its report <i>Animal Biotechnology: Science based Concerns</i> .
Dec. 2002	The Canadian government release a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports
Oct. 2002	(Oct 31) The Federal Government’s response to the Standing Committee on Health’s study entitled “ <i>Labeling of genetically modified foods and its impact on farmers</i> ” was tabled in the House of Commons on October 31, 2002 (Health Canada, 2006b).

~ 2003 ~	
Jan. 2003	Health Canada release an Issues Identification Paper to serve as a basis for discussion with stakeholders to identify the issues being addressed by the Government of Canada and to set out the goals and objectives for the Environmental Assessment Regulations (Health Canada, 2011b).
Mar. - May 2003	(March – May) The Standing Committee on Health study <i>Labeling of genetically modified foods and its impact on farmers</i> is resumed with participation from Health Canada. The Committee agrees not to pursue its study further after hearing an update from the chair of the CGSB on the development of a voluntary labeling standard (Health Canada, 2006c).
Apr, 2003	CIELAP release <i>Involving the Public in the Canadian Biotechnology Policy Process</i> (CIELAP, 2003). Fisheries and Oceans states in an internal audit document that the target date for the regulations for GE fish is 2005 (Commissioner of the Environment and Sustainable Development, 2004b)
June 2003	The Canadian government release a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports
July 2003	The release of Health Canada’s <i>Final Issue Identification Paper</i> regarding the creation of the EARs. The release of Health Canada’s revised <i>Guidelines for the Safety Assessment of Novel Foods</i> . Public online consultations regarding the revised <i>Guidelines for the Safety Assessment of Novel Foods</i> are held from July 15 th to September 30 th 2003 (Health Canada, 2006g).
July 2003	Greenpeace submits <i>Petition No. 84: Effects of GE crops on soil health; Petition No. 85: GE crops and products: trade concerns and other international matters</i> and <i>petition No. 88: GE wheat and the future of Canadian agriculture</i> .
Sept. 2003	(Sept 8) CGSB announce they have reached an agreement on a voluntary labeling standard for GE foods. (Sept 24) Health Canada’s Food Directorate publishes its <i>Interim Policy on Foods from Cloned Animals</i> . The interim policy considers foods produced from livestock developed using the technique of somatic cell nuclear transfer (SCNT) to be captured under the definition of “novel food” and therefore subject to <i>Novel Food Regulations</i> . Developers of cloned animals are requested to “withhold novel food notifications until requirements are determined and further guidance is available” (Health Canada. Food Directorate. Health Products and Food Branch, 2003).

	<p>Greenpeace submits <i>Petition 38B - Follow-up petition on genetically engineered fish</i></p> <p>Greenpeace submits <i>Petition No. 94: biotechnology and “pharming” crops</i></p>
Oct. 2003	<p>The Consumers Association of Canada’s national poll on the labeling of genetically modified foods found 88% of Canadians wanted mandatory labeling on GE food products source (Canada Newswire, 2003).</p> <p>The Notice of Submission Pilot project begins. Novel foods going through the approval process would now be listed on Health Canada’s website and made available for public comment.</p>
Nov. 2003	<p>(Nov 8) William Leiss, Chair of the Royal Society of Canada and co-chair of the Expert Panel on the Future of Food Biotechnology, reiterates the Expert Panel’s findings in his paper <i>The Case for Mandatory Labeling of Genetically-Modified Foods</i> (2003). The paper discussed the self-defeating approach of making a voluntary labeling standard (Leiss, 2003, p. 17).</p>
Dec. 2003	<p>The Canadian government releases a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports.</p>
<p>~ 2004 ~</p>	
2004	<p>The CFIA and Health Canada launch a project “to post on the CFIA website ‘notices of submission’ to describe the product and the data they receive from certain product developers who have requested safety assessments of plants with novel traits (PNTs) for unconfined release and safety assessments of novel feeds and novel foods derived from PNTs” (CFIA, 2009a). According to the CFIA’s website, the purpose of the project is:</p> <ul style="list-style-type: none"> - to give the public an opportunity to provide input on scientific matters relevant to the safety assessment of each submission - to increase transparency of the regulatory process - to increase confidence in the regulatory system with respect to PNTs, and novel feeds and novel foods derived from PNTs - to support the commitment to achieve greater openness regarding product information made by the Government of Canada in its responses to the Royal Society of Canada’s (RSC) Expert Panel Report titled, <i>Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada</i>, as well as those identified in the Canadian Biotechnology Advisory Committee (CBAC) report, called <i>Improving the Regulation of Genetically Modified and Other Novel Foods in Canada</i> (CFIA, 2009a)

	<p>The project is based on members of CropLife Canada volunteering to write the notices of submissions that would accompany their submissions to the CFIA and Health Canada “to demonstrate their support and understanding of the public desire for more transparency in the regulatory system” (CFIA, 2009a). According to CFIA’s website “Scientific questions or information will be forwarded to CFIA and Health Canada evaluators for consideration in the assessment. Non-scientific input will be evaluated and appropriate ways of addressing it will be explored” (CFIA, 2009a).</p> <p>Experimental GM pharma-pigs from the Quebec company TGN Biotech are accidentally turned into chicken feed instead of being incinerated. (Sharratt, 2010).</p> <p>The Public Advisory Committee of the Health Products and Food Branch is closed.</p>
Jan, 2004	Fisheries and Oceans Canada states in its response to petition No. 28B that it is developing regulations for GE fish (Commissioner of the Environment and Sustainable Development, 2004b).
Mar. 2004	CFIA’s Animal Biotechnology Focus Group Meeting is held. It is presented as an effort to “streamline” the regulatory approach to animal biotechnology (Andrée and Sharratt, 2004, p. 21).
Apr. 2004	(Apr 14) The enactment of Canada’s <i>Voluntary Labeling Standard for Genetically Engineered foods</i> . Proponents of the food biotechnology industry dominated the voting committee. ¹⁰ The unbalanced nature of the voting committee went against CGSB policies for balanced representation. ¹¹
Apr. 2004	Citizen Anna Kirkpatrick submits <i>Petition No. 108: Human, social and environmental impacts of genetic engineering:</i>
May 2004	The Departments of Fisheries and Oceans Canada (DFO), Environment Canada (EC) and Health Canada (HC) sign a Memorandum of Understanding respecting the implementation of the <i>NSNR (Organisms)</i> for certain aquatic living organisms.
June 2004	“Fisheries and Oceans Canada states that it cannot give a timeline for completing the regulations [for GE fish]” (Commissioner of the Environment and Sustainable Development, 2004b).
Aug. 2004	The Canadian government release a Progress Report in response to the Royal Society of Canada Expert Panel Report Progress Reports

¹⁰ This information was made available by ATI requests completed by Bradford Duplisea of the Canadian Health Coalition (CHC).

¹¹ The CGSB has a section on “Balanced Representation” in their CGSB Policy Manual for the Development and Maintenance of Standards (1994).

	The Submission of <i>Petition 125 – Federal regulation of genetically modified organisms</i>
Oct. 2004	Dr. Peter Andrée and Lucy Sharratt Coordinator CBAN, release a 53-page report that tracked what the Government had and had not done to implement the RSC Panel’s recommendations and stressed the fact that there had not been a public debate (Andrée and Sharratt, 2004). They also noted that requesting to keep animals out of the food system was clearly insufficient due to the contamination of research animals in the food supply (Andrée and Sharratt, 2004, p. 21). (Oct 29) CFIA publishes the revised <i>Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits</i> .
Oct. 2004	(Oct 30) The Minister of the Environment publishes in the <i>Canada Gazette, Part I</i> , the proposed <i>New Substance Notification Regulations (Organisms)</i> .
~ 2005 ~	
2005	CFIA employees write the journal article <i>Regulatory considerations for biotechnology derived animals in Canada</i> . The article stated “The need to ensure the biosafety of genetically engineered animals is one of the most critical challenges that the agricultural biotechnology industry and regulatory agencies face” (Kochhar, Adlakha-Hutcheon, & Evans, 2005, p. 117).
Feb. 2005	The Canadian Government responses to the RSC report through an Action Plan
June 2005	The last Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report Progress Reports was issued. Health Canada releases <i>Options Analysis Paper (OAP) - An Environmental Assessment Regime for New Substances in Products Regulated under the Food and Drugs Act</i> This paper was released to obtain feedback on the legislative authority under which the Environmental Assessment Regulations should be placed(Health Canada, 2011a). (June – Sept 30) The period of time for stakeholder feedback in regards to the Health Canada’s <i>Options Analysis Paper (OAP) - An Environmental Assessment Regime for New Substances in Products Regulated under the Food & Drugs Act</i>
July 2005	(July 8) Greenpeace submits <i>Petition 152 – Full access to information used for decisions on genetically modified organisms</i>
Sept. 2005	(Sept 21) The <i>New Substance Notification Regulations (Organisms)</i> is published in the <i>Canada Gazette, Part II</i> .

~ 2006 ~	
2006	<p>A survey by Decima Research concludes that 58 percent of Canadians believed that biotech animals will make life worse over the next twenty years, 54 percent held the same view of biotech fish, and 50 percent believe their future will be negatively impacted by biotech food (Martin and Grey, 2010).</p> <p>In <i>An Analysis of Efforts to Improve Genetically Modified Food Regulation in Canada</i> which appeared in the <i>Journal Science and Public Policy</i> (2006) the author Dr. Peter Andrée concludes that, “while some efforts have indeed been made, the Government of Canada continues to fall far short of meeting the RSC Panel’s expectations in key areas, including food safety, environmental assessment, peer review, transparency, and monitoring and surveillance” (Andrée, 2006, p. 1).</p> <p>The Enactment of the Federal Accountability Act. The Act acknowledges the need to integrate environmental, economic, and social factors in the making of all decisions by government.</p> <p>The Enactment of the Federal Sustainable Development Act.</p>
Feb. 2006	Health Canada releases its <i>Options Analysis Paper Feedback Analysis Report</i> to provide “an analysis and summary of the comments from stakeholders on the regulatory options, the critical issues and their components, and other issues of concern” (Health Canada, 2006e, p. 4).
Mar. 2006	(Mar 13) Health Canada releases an Environmental Impact Initiatives Discussion Document for the March 29 and 30 2006 Stakeholder Consultations on <i>The Development of Environmental Assessment Regulations for New Substances Contained in Products Regulated under the Food & Drugs Act</i>
June 2006	Health Canada releases its updated <i>Guidelines for the Safety Assessment of Novel Foods</i> “to reflect the advancement of methods and knowledge regarding product review” (Health Canada, 2012d). The 2006 <i>Guidelines for the Safety Assessment of Novel Foods</i> (Volumes I and II) stated that the section for Novel Foods Derived from Animals is “Under Development” (Health Canada. Food Directorate. Health Products and Food Branch, 2006) “Manufacturers or importers of novel foods derived from animal sources should consult with the Food Directorate to discuss what information is appropriate to the evaluation of the safety of a particular product” (Health Canada. Food Directorate. Health Products and Food Branch, 2006).
Sept. 2006	The CBAC released the report <i>Toward a Canadian action agenda for biotechnology: a report from the Canadian Biotechnology Advisory Committee.</i>
~ 2007 ~	
Mar. 2007	(Mar 26-28) The Environmental Assessment Working Group (EAWG) holds a

	meeting in Ottawa
May 2007	The CBAC's mandate concludes with the release of the Government of Canada's Science and technology Strategy.
Oct. 2007	(Oct 18-19) The Environmental Assessment Working Group (EAWG) holds a meeting in Ottawa
Dec. 2007	Announcement of the Food and Consumer Safety Action Plan. The 2008 Budget invested \$113 million over two years in the Food and Consumer Safety Action Plan (Prime Minister of Canada, 2007).
~ 2008 ~	
2008	<p>Limitations regarding the ability of regulatory bodies to regulate biotechnology-produced fish used for research are raised in the Auditor General's Office's 2008 audit report (Commissioner of the Environment and Sustainable Development, 2008).</p> <p>A survey by BIOTECCanada, a biotech industry group, states 79 percent of Canadians agree that "biotechnology" would bring benefits to agriculture (Martin and Grey, 2010).</p>
Jan. 2008	Technical consultations are held for the Food and Consumer Safety Action Plan (Treasury Board of Canada Secretariat, 2012).
Feb. 2008	(Feb 12) The Environmental Assessment Working Group (EAWG) holds a meeting in Ottawa via teleconference.
Mar. 2008	The launch of the Food and Drugs Act Liaison Office.
Apr. 2008	(Apr 8) The Prime Minister announces tougher food and product safety legislation to protect Canadian consumers (Prime Minister of Canada, 2008).
Apr. 2008	Gilles-André Perron Bloc Québécois MP for Rivière-des-Mille-Îles proposes Private Member's Bill C-517 to establish a new definition of genetically modified (GM) food and to require the mandatory labeling of Genetically Modified food.
May 2008	(May 7) Bill C-517, which would have given consumers the right to know if the food sold in Canada contains genetically engineered (GE) ingredients, was defeated in the House of Commons by a vote of 101 to 156 after its second reading (Greenpeace, 2008).
June 2008	(Jun 7-8) Release of the Environmental Assessment Working Group report <i>Scientific and Regulatory Considerations (SARC) documents pending for National Health Products (NHPs) and Novel Foods and Additives</i> .

July 2008	The Federal, provincial and territorial (FPT) governments announced the signing of a five-year agreement on agriculture called <i>Growing Forward</i> , a strategic framework encompassing the policies and programs put in place to support the Canadian agriculture and agri-food sector. <i>Growing Forward</i> replaced Canada's original agriculture policy, the Agricultural Policy Framework (APF). <i>Growing Forward</i> concludes on March 31, 2013 and its successor, <i>Growing Forward 2</i> , will take effect April 1 st 2013 (Standing Committee on Agriculture and Agri-Food, 2012, p. 1).
Aug. 2008	A Listeriosis outbreak centered on meat products produced by Maple Leaf Foods resulted in the death of 22 Canadians.
~ 2009 ~	
2009	Genetically Modified (GM) flax contamination found in Canadian flax exports to Europe lead to the European market closing its doors to Canadian flax (CBAN, 2012b). This was done at the request of the Flax Council of Canada and Saskatchewan Flax Development Commission which were concerned about losing the European market (CBAN, 2012b). Approximately 60% of Canada's yearly flax exports went to Europe (CBAN, 2012b).
Jan. 2009	Appointment of Sheila Weatherill, Independent Investigator, to conduct an investigation into the August 2008 Listeriosis outbreak that centered on meat products produced by Maple Leaf Foods.
Jan. 2009	The University of Guelph submits paperwork for the reproduction and exportation of Enviropig™ via a "Significant New Activity Notice".
Apr. 2009	The University of Guelph submits an application to Health Canada to approve its genetically engineered Enviropig™ for human consumption. No mandatory deadline for a decision was given (Mann, 2011).
May 2009	Internal DFO media lines are prepared in case of journalists' questions about AquaBounty. The media lines state that the Canadian regulations "currently provide an effective regulatory framework for protecting the environment from potential risks of GE fish" (Schmidt, 2011c).
June 2009	(Jun 30) Canada's <i>Organic Products Regulations</i> are set in place. The regulations "require mandatory certification to the revised National Organic Standard for agricultural products represented as organic in international and inter-provincial trade, or that bear the federal organic agricultural product legend (or federal logo)" (CFIA, 2001c). Approval of a biotech maize named Smartstax™ for release in Canada by the CFIA. The maize has eight different gene coding for several pest resistant and herbicide tolerant traits. As each GM trait had been individually approved in earlier crops by Health Canada, Health Canada did not classify the GE SmartStax™ as a

	“novel food”. The GE maize was approved for release by the CFIA, without approval from Health Canada. The GE maize was approved for environmental release by the Canadian Food Inspection Agency without an environmental risk assessment (CBAN, 2012a).
July 2009	(July 20) Sheila Weatherill, Independent Investigator, submitted her report to the Minister of Agriculture and Agri-Food that investigated the August 2008 Listeriosis outbreak that centered on meat products produced by Maple Leaf Foods
Nov. 2009	MP Alex Atamanenko, who at the time was the MP for BC Southern Interior and the NDP Agriculture Critic, introduces Private Member’s Bill C-474 to “amend the Seed regulations to require an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted” (Bill C-474, 2009). The bill was “a response to the fact that the introduction of certain genetically engineered(GE) organisms can put Canada’s export markets at risk but that current regulation does not consider this question of potential negative economic impacts” (CBAN, n.d.). In an interview for this research project Atamanenko stated that the Bill had attracted a lot of attention because thousands of people sent him e-mails and letters of support and sent letters to the Government (NDP-A).
~ 2010 ~	
2010	Approval, for the first time in Canada, of a GE Animal, the Enviropig™ developed at the University of Guelph, for reproduction and exportation under <i>New Substance Notification Regulations (Organisms)</i> .
Feb. 2010	Significant New Activity Notice provisions for the Enviropig™ are published in the Canada Gazette, Part I. Agriculture Canada commission a telephone survey “after Government officials hosted a series of meetings with AquaBounty Technologies Inc., as part of pre-notification consultations with the company concerning the human consumption of the animals” (Schmidt, 2011a). A telephone survey of 812 Canadians between Jan. 31 and February 11 is conducted by Harris/Decima. “Results are considered accurate to within 3.4 per cent, 19 times out of 20” (Schmidt, 2011a).
Mar. 2010	The National Farmers Union of Ontario passed a Resolution that they “oppose the commercial production of the Enviropig™ in Canada and request that Ontario Pork and OMAFRA withdraw support for the Enviropig™ and the University of Guelph shut down the project immediately” (NFU Ontario, 2010, p.1).
Apr. 2010	A majority of MPs vote in favour that Bill C-474 to amend the Seed Act be read a second time and referred to the Standing Committee on Agriculture and Agri-Food.
May 2010	CBAN launch a Stop the Enviropig™ campaign that includes a petition, letters to be sent to MPs, articles, policy briefings, debates, and speaking tours. Lucy

	Sharratt from CBAN said that “Enviropig™ was allowed to happen because there has never been a democratic debate in Canada about genetic engineering and there is no public overview of the direction of public research” (Sharratt, 2010).
Aug. 2010	A draft of the media lines prepared by the CFIA state: "The GE salmon are bred in contained, land-based systems and are reproductively sterile females, eliminating the threat of interbreeding amongst them or with native populations” (Schmidt, 2011c).
Aug. 2010	The <i>Guidelines for the Notification and Testing of New Substances: Organisms</i> were published pursuant to the <i>NSNR (Organisms)</i> under CEPA, 1999. According to the guidelines any request to develop biotechnology-produced fish for commercial purposes would be subject to the <i>NSNR</i> under CEPA, 1999 (Government of Canada, 2010).
Sept. 2010	<p>The Canadian Institute of Environmental Law and Policy (CIELAP) file <i>Petition No. 305: Accountability for Labeling of Genetically Modified Organisms</i>.</p> <p>The U.S. Food and Drug Administration hold public hearings regarding the AquaAdvantage® salmon. Documents are release revealing that AquaBounty plans to produce all its GM salmon eggs in Prince Edward Island (PEI) and ship the eggs to Panama for grow-out and processing. The company was not asking for approval to grow the fish in the U.S.A (CBAN, n.d.2; Patterson 2011). Lucy Sharratt, CBAN’s coordinator stated</p> <p>AquaBounty has so far avoided a full environmental review by splitting its proposal between the U.S., Canada and Panama... Canada’s decision on GM salmon eggs is critical to the future of Atlantic salmon around the world, but Environment Canada remains silent on the risks and any review they might be conducting. Meanwhile, AquaBounty has assumed it will get approval to produce its GM salmon eggs in PEI (CBAN, n.d.2).</p> <p>A joint motion to start a new study on biotechnology to be completed by the Standing Committee on Agriculture & Agri-food was introduced by Liberals and Conservatives to have the Standing Committee on Agriculture and Agri-Food conduct a study on the status of the Canadian biotechnology sector (Canada. Standing Common on Agriculture and Agri-Food, 2010).</p> <p>Ruth Salmon states in a CBC interview on behalf of CBAN and the Canadian Aquatic Industry Alliance said that "the Canadian aquaculture industry does not support the commercial production of transgenic fish for human consumption” (Sharratt 2010b).</p> <p>The Food Regulatory Advisory Committee hold their inaugural meeting</p>
Oct. 2010	CBAN and Beyond Factory Farming release a 7 page report on the Enviropig <i>Genetically Engineering Pigs to Support Industrial Production</i> .

	<p>(Oct 7) CBAN's coordinator Lucy Sharratt and Sean McGivern, then Regional Coordinator of the National Farmers Union Ontario debate Rich Moccia VP Research, University of Guelph and Dr. Cecil Forsberg, the creator of the Enviropig™. The topic of the debate was "Enviropig: Helpful or Harmful?" The event is organized by University of Guelph students and hosted by the Critical Knowledge Collective at the University of Guelph (Giacomini, 2011, p. 12).</p>
Nov. 2010	<p>(Nov11- 28) The CFIA conduct a survey on food safety.</p> <p>(Nov 16) The P.E.I. Coalition for a GMO Free Province, an NGO, send a letter to P.E.I. Premier Robert Ghiz requesting that that the Premier take action for PEI residents, and insist that Environment Canada disclose if they are already assessing GE salmon eggs for production on PEI. (Broderick, Labchuk & Boyd, 2010).</p> <p>(Nov 18) Agriculture Minister Gerry Ritz announced that the Government of Canada has taken a step to strengthen Canada's food safety system by appointing seven advisors to the Ministerial Advisory Board (MAB) of the CFIA.</p>
Dec. 2010	<p>The biotech industry hold fifty meetings in December 2010 with Liberal and Conservative MPs to lobby against bill C-474 (NDP-A).</p> <p>(Dec 1) The New Democratic Party used an obscure rule to secure an extended debate in the House of Commons of up to five hours on Bill C-474 for early in 2011.</p> <p>(Dec 6) The Food Regulatory Advisory Committee hold a meeting</p> <p>(Dec – Mar 2011) The House of Commons Agriculture Committee holds 10 public hearings on Bill C-474. A theme that had been addressed during the hearings was the need for greater transparency.</p> <p>Some witnesses stressed the need for transparency in regulatory decisions so that everyone has confidence in the system. They stated that regulatory authorities examine all new scientific data, but that information is not in the public domain. Neither the public nor independent scientists have access to the scientific data the government evaluates. For now, regulatory authorities are required by law to keep confidential any information produced by a commercial venture. The witnesses talked about the need to come up with ways of making scientific data accessible. Peers could review scientific protocols and replicate experiments, and that would improve the regulatory process. (Canada, 2012, p. 51)</p> <p>Sixty-three fisheries and oceans conservation, environmental and social justice groups released a joint statement in December 2010 opposing GM fish (Donnelly, 2011).</p>
Dec. 2010	<p>(Dec 8) Agriculture Minister Gerry Ritz launches a roundtable "focused on giving consumers an additional opportunity to raise concerns and discuss ways to further improve Canada's food safety system. This new forum is another way the</p>

	<p>Government of Canada is improving transparency, consultations and communications with Canadians, as recommended by the 2008 report of the independent investigator, Sheila Weatherill (CFIA, 2010b)</p> <p>CBAN give a briefing to the House of Commons Standing Committee on Agriculture and Agri-Food <i>Genetically Engineered Organisms: The Need to Consider Potential Economic Harm Prior to Commercial Release</i></p>
~ 2011 ~	
2011	The Federal Government hold consultations on Low Level Presence, “the unintended presence, at low levels, of a genetically modified (GM) crop that is authorized for commercial use or sale in one or more countries, but is not yet authorized in an importing country” (AAFC, n.d. p. 3).
2011	A commitment of \$100 million over five years is made to invest in inspector training, tools and technology, and science capacity concerning food safety (CFIA, 2011a).
Jan. 2011	A meeting takes place between a coalition of opponents to AquaBounty plans (including the Council of Canadians, P.E.I. Health Coalition, the CBAN and Earth Action PEI), P.E.I. Premier Robert Ghiz and P.E.I. Provincial Environment Minister Richard Brown. The group asked Ghiz to address “growing opposition to AquaBounty's development of GMO salmon in P.E.I.” (CBC News, 2011).
Feb. 2011	Bill C-474 was debated and voted on in the House of Commons while many Agriculture Committee members were on the road. The bill was defeated in its third reading, the farthest a Private Members Bill on genetic engineering has gone in the Parliamentary process (CBAN, 2012b).
Feb. 2011	<p>(Feb 9) Over 150 people participate in the “Pig Rally: Stop U of G’s Enviropig™” sponsored by the OPIRG Guelph (Ontario Public Interest Research Group) student group as well as the Ecological Farmers of Ontario, the National Farmers Union Ontario, The Big Carrot NaturalMarket in Toronto, CBAN, and The Council of Canadians Guelph Chapter (CBAN, 2011c).</p> <p>(Feb 23) Journalist Sarah Schmidt writes an article <i>GE salmon could harm our fish stocks: scientists</i> discussing an ATI request she did re DFO scientists.</p>
Mar. 2011	<p>Fin Donnelly NDP MP and Fisheries and Oceans Critic tabled motion M-648 in the House of Commons “asking for transparency and more study before genetically modified (GM) Atlantic salmon are approved for human consumption.”</p> <p>M-648 — Mr. Donnelly — That, in the opinion of the House, the Government should immediately: (a) provide greater regulatory clarity by identifying which Government departments are responsible for the regulation of genetically modified salmon and other transgenic aquatic organisms; (b) prevent the introduction into</p>

	<p>the Canadian food system of genetically modified salmon destined for human consumption until further scientific studies are concluded by the relevant departments to determine the impact of genetically modified salmon on human health and on the health of marine species, ecosystems and habitats; and (c) direct the departments responsible for the regulation of genetically modified salmon to establish a practice of notifying the Canadian public of all requests and approvals and of any information and findings regarding genetically modified salmon and salmon eggs. (CBAN, 2011a)</p> <p>(Mar 2) Liberal Agriculture Critic Wayne Easter put forth a Motion for a Moratorium on GE Alfalfa</p> <p>The House of Commons Agriculture Committee held 10 public hearings on Bill C-474 between December 2010 and March 2011.</p>
Mar. 2011	(Mar 16) Agriculture Minister Gerry Ritz announces that the CFIA will begin to publish information about its compliance and enforcement activities being taken to protect the safety of the Canadian food, animal and plant supply... ..This will give our inspectors another tool in the toolbox to shine the light of transparency on repeat offenders and companies that try and import unsafe food” (CFIA, 2011b).
May 2011	The House of Commons Agriculture Committee study on biotechnology comes to an end with the May 2, 2011 election of the 41 st Parliament. A full report with recommendations was not completed but a summary of results was included in the Standing Committee on Agriculture and Agri-Food report <i>Growing Forward 2</i> (2012).
June 2011	(June 23) The first reading of NDP MP Alex Atamanenko’s Bill C-257 to amend the food and Drugs Act for the mandatory labeling of genetically modified foods (<i>Bill C-257</i> , 2011).
June 2011	(June 1-2) The Food Regulatory Advisory Committee holds a meeting. Members decide to rename the Committee the Food Expert Advisory Committee (FEAC) to better reflect its mandate.
July 2011	(July 5) Voluntary labeling guidelines for GE foods were issued by the Codex Alimentarius Commission.
July 2011	(July 20) The release of the CFIA Public Opinion Research Final Report <i>Food Safety: Canadians’ Awareness, Attitudes and Behaviours</i> .
Sept. 2011	CFIA’s release a press release <i>Food Safety Confidence in Canada on the Rise</i> stating “Canadians remain confident in Canada’s food safety system, according to results from a recent survey conducted by Leger Marketing in the spring of 2011. Sixty-eight per cent of Canadians gave the system a favourable confidence rating. That is up from 65 per cent in 2010 and 60 per cent in 2008” (CFIA, 2011a).The press release quotes Agriculture Minister Gerry Ritz as stating “The

	<p>Canadian food safety system works well and the majority of Canadians acknowledge that. They have confidence in Canadian standards, regulations and processes” (CFIA, 2011a).</p>
Sept. 2011	<p>(Sept 20) Advocacy Day takes place in Ottawa “to raise awareness of the biotechnology industry and to foster ongoing support of public policy within multiple levels of government” (PEI BioAlliance, 2011)</p>
Oct. 2011	<p>(Oct 4) Journalist Sarah Schmidt article <i>Canadian Skeptical of government’s ability to regulate GM animals</i></p> <p>(Oct 17) Journalist Sarah Schmidt article <i>GE fish may pose risk to wild stock: documents</i>. Schmidt states that Environment Canada had admitted the department “isn’t sure it can fully protect wild fish stocks if it approves the commercialization of the hatchery for genetically engineered salmon eggs” (Schmidt 2011b).</p> <p>Schmidt reports that according to the internal records</p> <p>Environment Canada concluded that the narrower oversight option - while ‘easily enforceable by inspecting shipments at the port of export’ in Canada – ‘falls short’ of meeting Canada’s legal obligations under CEPA ‘because it does not fully consider potential effects within Canada’. (Schmidt 2011b).</p> <p>Journalist Sarah Schmidt also releases articles stating internal records obtained through the ATI Act revealed senior scientists specializing in biotechnology and aquaculture from the Department of Fisheries and Oceans “are concerned about ‘limited’ and possibly ‘constrained’ regulatory powers around the approvals for GE fish (Schmidt, 2011c).</p> <p>Schmidt also releases articles comparing DFOs internal media line from May 2009 with CFIA’s from August 2010. Internal DFO media lines that were prepared in May 2009 in case of journalists' questions about AquaBounty stated that the Canadian regulations "currently provide an effective regulatory framework for protecting the environment from potential risks of GE fish” (Schmidt, 2011). A draft of the media lines prepared by the CFIA in August of 2010, stated: "The GE salmon are bred in contained, land-based systems and are reproductively sterile females, eliminating the threat of interbreeding amongst them or with native populations” (Schmidt, 2011c). Schmidt’s article identified concerns from a DFO scientist over the changes to the media lines.</p> <p>A representative from the Council of Canadians gives a presentation on the topic of the AquaAdvantage® salmon to the House of Commons Agricultural Committee in a lot of questions were received that zeroed in on GE Salmon. The representative was one of a few presenters (NGO-2).</p> <p>(Oct 24 – 27) A 4-city speaking tour took place against the pending approval of GM fish. Featured speakers include Eric Hoffman, Biotechnology Policy</p>

	Campaigner, Friends of the Earth U.S., Washington DC, Jaydee Hanson, Senior Policy Analyst, Center for Food Safety, Washington DC, Lucy Sharratt, Coordinator, Canadian Biotechnology Action Network, Ottawa and Leo Broderick, Vice Chair, Council of Canadians, PEI (Patterson, 2011)
Nov. 2011	(Nov 1) Agriculture Canada organizes stakeholder consultations on “Low Level Presence” to allow a percent, 0.1% or higher, of food to be contaminated with genetically modified (GM) foods that have not been approved by Health Canada for safe human consumption. A Comment period was held until November 25 (AAFC, n.d.; Schmidt, 2012).
~ 2012 ~	
2012	<p>The Agriculture Committee’s releases its <i>Growing Forward 2</i> report. <i>Growing Forward 2</i> will replace <i>Growing Forward</i> on April 1st 2013 (Standing Committee on Agriculture and Agri-Foods, 2012).</p> <p>In a Dissention opinion attached to <i>Growing Forward 2</i> the NDP party recommended</p> <p>That the government undertake a comprehensive review of the regulations governing GE seeds, fish and animals with a view to:</p> <ul style="list-style-type: none"> - Implementing the Royal Society of Canada’s 58 recommendations - Introducing transparency in the scientific reviews and approval processes - Creating a mechanism to consider market implications in the approval process - Creating a separate category of regulations to govern GE seeds, fish and animals - That an independent body be created to peer-review relevant scientific data - Impose an immediate moratorium on GE food/ animals/fish, alfalfa and wheat until such time as a regulatory review has been conducted and modernized rules brought into effect. (Standing Committee on Agriculture and Agri-Foods, 2012, p. 80) <p>Enviropig™ were slaughtered and their semen frozen. The initiative was undertaken by the University of Guelph due to a lack of funding for their research (Leung, 2012).</p> <p>The French group of Gilles-Eric Seralini conduct a peer-reviewed study that describes harmful effects on rats fed on diets containing GE maize. (Seralini, et al., 2012). This study was the first biotechnology-produced animal feeding trial that had been conducted over the lifetime of laboratory rats (two years) to test</p>

	Monsanto's GM corn NK603 and their herbicide Roundup, approved in Canada in 2001.
Sept. 2012	The Federal Government's "draft plan for managing the low-level presence of GMOs in food and feed products" is to be submitted to the World Trade Organization in September (Schmidt, 2012). The research for this paper has been unable to find information on whether this happened.
Oct. 2012.	(Oct 25) The release of "Health Canada and Canadian Food Inspection Agency statement on the Séralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603" (Health Canada, 2012f).
Nov. 2012	<p>Canada's voluntary labeling standard for GE foods has not undergone review.</p> <p>The Europe Market is still closed to Canadian flax.</p> <p>Information has not been released concerning any requests made by AquaBounty Technologies Inc to approve its AquAdvantage® salmon for human consumption.</p> <p>It was anticipated that the proposed Environmental Assessment Regulations would be pre-published for comment in the <i>Canada Gazette</i>, Part I in 2011. The EARs have not been completed.</p> <p>Information has not been released whether Health Canada has made a decision on the Enviropig™ application.</p>

Appendix B: Selected Consultations

Health Canada's Environmental Assessment Regulations

Between September 1st and October 30th 2001 Health Canada held a comment period on the Notice of Intent it had published regarding the Environmental Assessment Regulations (EARs). In January 2003 the department released an *Issue Identification Paper* to serve as a basis for discussion with stakeholders to identify the issues being addressed by the Government of Canada and to set out the goals and objectives for the EARs' options (Health Canada, 2011a). This paper was followed by a *Final Issue Identification Paper* (July 2003) and an *Options Analysis Paper (OAP) - An Environmental Assessment Regime for New Substances in Products Regulated under the Food & Drugs Act* (June 2005). The Options Analysis Paper was to obtain feedback on the legislative authority under which the EARs should be placed (Health Canada, 2011a). Between June and September 2005 stakeholders were given the opportunity to provide feedback on the Option Analysis Paper. In February 2006 the *Options Analysis Paper Feedback Analysis Report* was released to provide "an analysis and summary of the comments from stakeholders on the regulatory options, the critical issues and their components, and other issues of concern" (Health Canada, 2006e, p. 4). A month later, in March 2006, Health Canada released a Discussion Document for Stakeholder Consultation held March 29 - 30, 2006 on *The Development of Environmental Assessment Regulations for New Substances Contained in Products Regulated under the Food & Drugs Act*

Guidelines for the Safety Assessment of Novel Foods

The *Guidelines for the Safety Assessment of Novel Foods* (Volumes I and II) have undergone review on multiple occasions. A draft version of the *Guidelines for the Safety Assessment of Novel Foods derived from Plants and Microorganisms* was released in August 2002 and a revised version was published in July 2003. Public online consultations regarding the Guidelines were held from July 15th to September 30th 2003 (Health Canada, 2006g).

Labeling Genetically Engineered Foods

CFIA's website states that a set of guidelines were developed based on three major consultations on the labeling of novel foods derived from genetic engineering that had taken

place since 1993 (CFIA, 2012d). The guidelines “reflect a general consensus to: require mandatory labeling if there is a health or safety concern, i.e., from allergens or a significant nutrient or compositional change (these decisions will be made by Health Canada), in order to inform consumers of the allergen or change” and to permit voluntary negative and positive labeling “on the condition that the claim is not misleading or deceptive and the claim itself is factual” (CFIA, 2012d).

Appendix C: Selected Polls

A 1994 poll commissioned by Industry Canada showed that up to 95% of Canadian consumers wanted labels on GE Foods (Council of Canadians, 1999).

In June of 1999 a Prairie Research Associates poll released showed 92% of Manitobans want labeling (77% of those polled believed GE foods were unsafe or were unsure of their safety) (Council of Canadians, 2011).

In December of 1999 a Montreal Gazette poll of 966 Montrealers found almost unanimous support for a mandatory GE food label. Over 50% of the respondents thought that GE foods should be banned (Abley 2000).

In May of 2001 a poll conducted by Pollara & Earncliffe Research and Communications for the Globe and Mail shows that 94% of Canadians believed the government should order companies to label GM foods (MacKinnon, 2001).

In 2002 a Pew Global Attitudes Project survey reported that 37% of Canadians viewed scientifically altered fruits and vegetables as good, whereas 63% thought these products were bad (Martin and Grey, 2010).

In October of 2003 The Consumers Association of Canada's national poll on the labeling of genetically modified foods found 88% of Canadians wanted mandatory labeling on GE food products (Canada Newswire, 2003)

A 2006 A survey done by Decima Research concludes that 58% of Canadians believed that biotech animals will make life worse over the next twenty years, 54 percent held the same view of biotech fish, and 50 percent believe their future will be negatively impacted by biotech food (Martin and Grey, 2010).

A 2008 survey by BIOTECCanada, a biotech industry group, stated 79% of Canadians agreed that "biotechnology" would bring benefits to agriculture (Martin and Grey, 2010).

Appendix D: Interview Questions

Office of the Auditor General

1. Would the Commissioner of the Environment and Sustainable Development be involved with concerns over how transparent the decision-making process of the Federal Government is with respect to the human consumption of animals produced through biotechnology?
2. If yes, has the Commissioner of the Environment and Sustainable Development brought to attention any issues concerning the transparency of the decision-making process of the Federal Government?
3. Is information available concerning decisions your departments has made or is making with regards to novel foods derived from animals?

Members of the Official Opposition Party

1. Does your party hold any concerns over how transparent the decision-making process of the Federal Government is?
 - a) If yes - Has the opposition utilized methods (motion days, question periods etc) to shed light on these concerns?
 - b) If yes - What methods were utilized?
 - c) Were the efforts successful?
 - d) Is your party planning on utilizing methods?
2. Does the opposition party hold any concerns over how transparent the decision-making process of the Federal Government is with respect to the human consumption of animals produced through biotechnology?
 - a) If yes - Has the opposition utilized methods (motion days, question periods etc) to shed light on these concerns?
 - b) If yes - What methods were utilized?
 - c) Were the efforts successful?
3. Is there anything else you would like to say regarding the topic of transparency in the Federal Government, or policy making surrounding the human consumption of genetically engineered animals?
4. Is information available concerning decisions your departments has made or is making with regards to novel foods derived from animals?

Representative from the Novel Foods Section Food Directorate, Health Products and Food Branch, Health Canada

Transparency Initiatives

1. What transparency initiatives have been or are being utilized regarding the development of the safety assessment criteria for novel foods derived from animals?
2. How successful have these initiatives been?
3. Are any other initiatives being considered to increase transparency throughout the decision-making process?

Obtaining Information on progress that has been made

4. The most up-to-date information that I can find regarding the pre-market safety assessment of novel foods are the 2006 guidelines. These guidelines state that “Safety assessment criteria for novel foods derived from animals are under development”. Is information available on progress that has been made since 2006?
5. How is the Food Directorate keeping the public informed regarding decisions that have been made or are being made with regards to novel foods derived from animals?
6. Is information available concerning decisions your departments has made or is making with regards to novel foods derived from animals?
7. Are any other departments providing information to the public regarding the development of safety assessment criteria for novel foods derived from animals?
8. The 2006 guidelines also state that “Manufacturers or importers of novel foods derived from animal sources should consult with the Food Directorate to discuss what information is appropriate to the evaluation of the safety of a particular product.” Is it possible to access the information the food directorate is providing applicants?

After decisions have been made

9. When the safety assessment criteria for novel foods derived from animals are finalized, how will the public be informed?

Stakeholder Involvement

10. What stakeholders have been invited to participate in deciding safety-assessment criteria for novel foods derived from animals, and what are their roles? What point(s) in decision-making are they involved with?

Inter-relationship

11. Do you know if Health Canada will postpone making a decision on approving the Enviropig™ for human consumption until the new pre-market safety-assessments are finalized?

Last thoughts

12. Is there anything else you'd like to add about the development of the safety assessment criteria for novel foods from animals?
13. Is there anyone else you think I should talk to?

Representatives from Health Canada's Environmental Impact Initiative (EII) within the Health Products and Food Branch (HPFB)

Transparency Initiatives

1. What transparency initiatives have been or are being utilized regarding the development of the EARs?
2. How successful have these initiatives been?
3. Are any other initiatives being considered to increase transparency throughout the decision-making process?

Obtaining Information on progress that has been made

4. The last document I could find regarding the development of the EARs was a discussion document for Stakeholder Consultations that took place on March 29th and 30th 2006. Is any information available in regards to these Consultations? Is information available on progress that has been made since 2006?
5. Is information available concerning decisions your departments has made or is making with regards to novel foods derived from animals?
6. How is the public being informed regarding decisions that have been made or are being made with regards to the development of the EARs?
7. Are any other departments providing information to the public with regards to the development of the EARs?

After decisions have been made

8. It was anticipated that the proposed Environmental Assessment Regulations would be pre-published for comment in the Canada Gazette, Part I in 2011. When do you think they would be released? Is there an up-dated timeline for the EARs?
9. When the EARs are finalized, how will the public be informed?

Stakeholder Involvement

10. What stakeholders have been invited to participate in decision making for the EARs, and what is their role? What point in decision-making are they involved with?

Information on the EARs

11. Will there be a separate section in the EARs for novel foods?
12. Will these regulations make the decision-making process regarding the human consumption of food derived through modern biotechnology more or less transparent than the process under the NSNR? (i.e. when companies have to submit data and the type of data companies are required to submit)

Inter-relationships

13. Environment Canada was in charge of the NSNR for the Enviropig. Does Environment Canada have a role regarding the EARs for novel foods?
14. If no, what happens if a food product containing biotechnology-produced animals gets approved before the EARs are implemented? if the Enviropig is approved for human consumption under the NSNR, would it have to be approved under the EARs once they are finalized?
15. Do you know if Health Canada will postpone making a decision on approving the Enviropig™ for human consumption until the EARs are finalized?

Last thoughts

16. Is there anything else you'd like to add about the development of the EARs in regards to novel foods from animals?
17. Is there anyone else you think I should talk to?

Representatives from Health Canada

Transparency Initiatives

1. What transparency initiatives have been or are being utilized regarding the development of regulations for novel foods derived from animals?
2. How successful have these initiatives been?
3. Are any other initiatives being considered to increase transparency throughout the decision-making process?
4. Is information available concerning decisions your departments has made or is making with regards to novel foods derived from animals?

Website

5. Has Health Canada put out an Action Plan in response to the Royal Society's Export Panel Report "*Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*" since June 2005?
6. Will Health Canada be updating its FAQs on biotechnology which was last updated in 2006? If yes, when might this done?

Enviropig application

7. What information is available to the public regarding the application submitted by the University of Guelph for the Enviropig™? How is that information being made available?
8. What information is available to the public concerning the process the application is going through?
9. What stage of the process is the Enviropig application going through?
10. What sections of Health Canada is responsible for making decisions concerning this application?
11. Are there any other federal departments or agencies that have responsibilities over the application?
12. EARs are being created and the safety assessment of Novel foods is under development concerning novel foods derived from animals. Are applications for novel foods derived from animals not going to be processed until these decisions are finalized?

After decisions have been made

13. How will the public be informed when a decision regarding the application has been made?

Public Advisory Committee

14. The Public Advisory Committee of the Health Products and Food Branch has been closed since 2004. Why was it closed? Is there another initiative that took over the role of the PAC?

15. Is there anyone in particular I should speak to about the PACs activities?

Last thoughts

16. Is there anything else you'd like to add?
17. Is there anyone else you think I should talk to?

Interview Questions for Non-Government Organizations

Canadian Biotechnology Action Network (CBAN)

1. Why did the CBAN become interested in the human consumption of biotechnology-produced animals in Canada?
2. What does the CBAN know about the decisions the Canadian government has made or is currently making concerning the human consumption of animals produced through biotechnology?
3. How did the CBAN come across this information?

Participation – Environment Assessment Regulations (EARs) and Human Safety Assessments

4. The government is currently updating its EARs and Pre-safety notification requirements. Has the CBAN participated in any activities concerning the development of Health Canada's Environmental Assessment Regulations for new substances contained in products regulated under the FDA?
5. Has the CBAN participated in any activities concerning the safety assessment of novel foods from animals?

Accessing Information

6. Have you or your organization attempted to obtain information on decisions the government is making or has made regarding the human consumption of animals produced through biotechnology?
7. Has the CBAN perceived or come across barriers to obtaining information about the decisions the Canadian government has made or is currently making concerning the human consumption of animals produced through biotechnology?
8. Has the CBAN been able to access all the information it wanted regarding this topic?
9. Is there any information the CBAN has been unable to obtain concerning decisions the Canadian government has made or is currently making concerning the human consumption of animals produced through biotechnology?
10. Was the CBAN denied access to any information it was trying to obtain regarding this topic? If yes, was the CBAN given reasons why it was denied access to the information?
11. Is the CBAN taking or considering taking additional measures to gain access to the information they were unable to obtain? (For example ATI Act)
12. What challenges has CBANs faced in its attempts to obtain information concerning this topic?
13. Following up on that question, has the CBAN attempted to obtain information regarding the University of Guelph's application to Health Canada for the Enviropig™? If so, what has your experience been in terms of access to information and transparency?

Participation

14. Have you or the CBAN been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
15. Have you or the CBAN participated in or attempted to participate in the policy process, either directly or indirectly?
16. Have you or the CBAN perceived or come across barriers to participating in a meaningful way?
17. Do you/your organization feel that you could effectively participate in the decision-making process? Are there any institutional or political barriers that would prevent this or do you feel that the process is inclusive?

Transparency

18. Does the CBAN think the government is making decisions in a transparent manner?
19. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
20. You have a long history with studying GE food regulation in Canada. In October 2004 you wrote a paper with Peter Andree entitled *Genetically Modified Organisms and precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?*. Is there anything you would like to say to elaborate on your findings? Do you know if the government has released an action plan since 2005?
21. You stated "Enviropig™ was allowed to happen because there has never been a democratic debate in Canada about genetic engineering." Do you think transparency is increasing or decreasing regarding GE food policy in Canada?
22. How do you think transparency in decision-making at the federal level regarding this topic could be increased?
23. In regards to ATI documents that were released concerning the AquAdvantage® salmon, you stated "This could be a case of good scientists inside departments constrained by regulations." What are your thoughts on the ability of institutions that are set up to hold the government accountable for decisions being made? (i.e. using the ATI Act to obtain information).
24. Can you identify, or have you come across any barriers to transparency that you have not mentioned? (regarding access to information, participating in decision-making, etc)
25. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
26. Is there anyone else you think I would benefit from talking to?

The Council of Canadians

1. What activities have the Council of Canadians undertaken with regards to the human consumption of animals produced through biotechnology?
2. Is the council currently involved in any activities?
3. have you or your organization attempted to obtain information on decisions the government is making or has made regarding the human consumption of animals produced through biotechnology?

4. Repeat of previous questions asked to representatives from NGOs (transparency questions, etc). The questions would stay the same but the names of participants would change.

The Canadian Aquatic Industry Alliance

Questions regarding information gathering

1. In a September 2010 interview you stated that "The Canadian aquaculture industry does not support the commercial production of transgenic fish for human consumption." Why did the CAIA feel the need to speak out about the human consumption of transgenic fish?
2. What does the CAIA know about the decisions the Canadian government has made or is currently making concerning the human consumption of animals produced through biotechnology?
3. How did the CAIA come across this information?
4. Has the CAIA attempted to obtain additional information regarding how transgenic fish would be approved for human consumption?
5. How successful was the CAIA in gather information regarding decisions the Federal Government has made or is currently making concerning the human consumption of transgenic fish?
6. Has the CAIA perceived or come across barriers to obtaining information?
7. Is the CAIA taking or considering taking additional measures to gain access to the information they were unable to obtain? (For example ATI Act)
8. What challenges has the CAIA faced in its attempts to obtain information concerning this topic?

Questions regarding Decision-making process

9. Have you or the CAIA been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
10. Have you or the CAIA participated in or attempted to participate in the policy process, either directly or indirectly?
11. Have you or the CAIA perceived or come across barriers to participating in a meaningful way?

12. Do you/your organization feel that you could realistically affect the decision-making process? Are there any institutional or political barriers that would prevent this or do you feel that the process is inclusive?

Transparency Questions

13. Do you think the government is making decisions in a transparent manner?
14. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
15. How do you think transparency in decision-making at the federal level regarding this topic could be increased?
16. What are your thoughts on the ATI documents released by PostMedia?
17. Can you identify, or have you come across any barriers to transparency? (regarding access to information, participating in decision-making, etc)
18. What are your thoughts on the ability of institutions that are set up to hold the government accountable for decisions being made? *ask this if they utilized institutions
19. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
20. Is there anyone else you think I would benefit from talking to?

The National Farmers Union

1. You've spoken out a great deal regarding the Enviropig on behalf of the National Farmers Union. Why is the NFU so interested in the Enviropig?
2. Has the NFU attempted to obtain information regarding the University of Guelph's application to Health Canada for the human consumption of the Enviropig™?

Questions regarding Decision-making process

3. Have the NFU been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
4. Have you or the NFU participated in or attempted to participate in the policy process, either directly or indirectly?

5. Have you or the NFU perceived or come across barriers to participating in a meaningful way?
6. Do you/your organization feel that you could effectively participate in the decision-making process? Are there any institutional or political barriers that would prevent this or do you feel that the process is inclusive?
7. What role would you like the NFU to take in the decision-making process?

Transparency Questions

8. Do you think the government is making decisions in a transparent manner?
9. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
10. How do you think transparency in decision-making at the federal level regarding this topic could be increased?
11. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
12. Is there anyone else you think I would benefit from talking to?

Interview Questions for Representatives from the Royal Society of Canada

1. The Royal Society's expert panel report entitled "Elements of Precaution: Recommendations on the Future of Food Biotechnology (2001)," included a lot of recommendations concerning the regulation of food products from transgenic animals. It also included a lot of recommendations concerning transparency. The Canadian government released a lot of reports in response to the expert panel. Are you familiar with these recommendations?
2. Are you familiar with the government's responses?
3. Do you know someone who would be better suited to ask about the response from the government?
4. What are your thoughts regarding the responses from the Canadian government?
5. Do you think the regulatory environment has become more transparent since the report was made?

6. The last response the government made with regards to the Royal Society's report was completed in June 2005. Do you know if there has been an Action Plan issued by the government since 2005?
7. Do you think there is a reason that the government stopped publishing reports on what it's doing?

Questions regarding Decision-making process

8. Since the initial report, has the Royal Society been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
9. Have the Royal Society participated in or attempted to participate in the policy process, either directly or indirectly?
10. Have the Royal Society perceived or come across barriers to participating in a meaningful way?
11. Do you/your organization feel that you could effectively participate in the decision-making process? Are there any institutional or political barriers that would prevent this or do you feel that the process is inclusive?

Transparency

12. Do you think the government is making decisions in a transparent manner?
13. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
14. Do you think transparency is increasing or decreasing regarding GE food policy in Canada?
15. How do you think transparency in decision-making at the federal level regarding this topic could be increased?
16. Can you identify, or have you come across any barriers to transparency that you have not mentioned? (regarding access to information, participating in decision-making, etc)
17. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
18. Is there anyone else you think I would benefit from talking to?

19. Will the report the Royal Society is working on entitled “Ocean Climate Change and Marine Biodiversity” take into account GE Fish? How?

Interview Questions for Journalists from Postmedia

1. In February of 2011 Sarah Schmidt wrote an article that talked of an ATI request that was made by Postmedia regarding meetings and subsequent discussions between AquaBounty and scientists in DFO. What information did Postmedia hope to obtain through its ATI request?
2. Why did Postmedia attempt to obtain this information?
3. Was Postmedia able to access all the information it wanted regarding this topic?
4. Do you know what reasons, if any, were given for sections of the documents obtained through the ATI Act being blocked out?
5. Did you try to gain access to the information they were unable to obtain through the ATI Act? If yes, what avenues did you utilize/attempt to use to obtain information?
6. What are your thoughts regarding your efforts to obtain this information?
7. Would it be possible for me to obtain a copy of the ATI request? (I will ask this before we set up an interview).
8. What are your thoughts on how the concerns scientists raised were treated?
9. Do you think the government is making decisions in a transparent manner?
10. How do you think transparency in decision-making at the federal level could be increased?
11. How transparent is the ATI process in terms of the public’s ability to hold the government accountable?
12. What are your thoughts on the ability of institutions that are set up to hold the government accountable for decisions being made? *ask this if they utilized institutions
13. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
14. Is there anyone else you think I would benefit from talking to?

Interview Questions for academia (Specialist in biotechnologies and public policy)

Questions regarding Decision-making process

1. You have spoken out against Health Canada's ability to assess GE animals. Do you think concerned stakeholders will have the opportunity to question Health Canada's ability to assess whether GE Animals should be approved for human consumption?
2. Have you been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
3. Have you attempted or are you going to attempt to participate in the decision-making process regarding how biotechnology-produced animals would be assessed for human consumption?
4. Have you perceived or come across barriers to participating in a meaningful way?
5. Do you feel that you could realistically affect the decision-making process?

Transparency

6. What are your thoughts on the ability of institutions that are set up to hold the government accountable for decisions being made?
7. Do you think the government is making decisions in a transparent manner?
8. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
9. How do you think transparency in decision-making at the federal level could be increased?
10. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?
11. Is there anyone else you think I would benefit from talking to?

Interview Questions for Canadian Researchers

1. In the past you have been very vocal when the government was making decisions concerning GE food. Are you involved, or planning on getting involved in the decision-making process regarding the human consumption of GE animals?

2. Why or why not?
3. Have you participated in any activities concerning the development of Health Canada's Environmental Assessment Regulations for new substances contained in products regulated under the FDA?
4. Have you participated in any activities concerning the safety assessment of novel foods?
5. What do you think about the information the Federal Government is providing to the public on its decision-making process regarding the human consumption of animals produced through biotechnology?

Questions regarding Decision-making process

6. Have you been given any opportunities to participate in or to influence the decision-making (i.e. policy-making) processes of the Federal Government regarding the human consumption of biotechnology-produced animals?
7. Have you participated in or attempted to participate in the policy process, either directly or indirectly?
8. Have you perceived or come across barriers to participating in a meaningful way?
9. Do you feel that you could effectively participate in the decision-making process? Are there any institutional or political barriers that would prevent this or do you feel that the process is inclusive?

Transparency Questions

10. Do you think the government is making decisions in a transparent manner?
11. How transparent would you say the process is in terms of the public's ability to hold the government accountable?
12. How transparent is the process in terms of the public's ability to hold the government accountable?
13. Do you think transparency is increasing or decreasing regarding GE food policy in Canada?
14. How do you think transparency in decision-making at the federal level regarding this topic could be increased?
15. Can you identify, or have you come across any barriers to transparency that you have not mentioned?

16. Is there anything else you would like to add regarding how transparent the decision-making process of the Federal Government is with respect to the human consumption of biotechnology-produced animals?

Interview Questions for Representatives from the Canadian Institute for Environmental Law and Policy (CIELAP)

1. What has CIELAP done to increase transparency in GE food policy making in Canada?
2. Why did CIELAP feel the need to undertake these projects? (for example – “A perspective and recommendations on biotechnology policy” written in 2008 by Holtz)
3. Did CIELAP experience any frustrating over the information the Federal Government was providing to the public concerning GE food policy making in Canada?
4. Do you think CIELAPs efforts affected any GE food policy outcome?
5. What are your thoughts on the government’s transparency initiatives towards GE food policies?
6. Do you think that the decision-making behind GE food policies in Canada are becoming more or less transparent?
7. In Sept 2010 CIELAP and The Canadian Council of Churches made a petition “accountability for labeling of GMOs” why did CIELAP find this necessary?
8. Are you currently involved in or attempting to be involved in the decision-making regarding the human consumption of biotechnology-produced animals?

Appendix E: Consent Form

By signing this consent form, you are not waiving your legal rights or releasing the investigator or involved institution from their legal and professional responsibilities.

I have read the information presented in the information letter about a research project being undertaken by Heather Lee of the Department of Environment and Resource Studies at the University of Waterloo. I have had the opportunity to ask any questions related to this project, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing my interview to be audio recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the interview may be included in the thesis and/or publications to come from this research, with the understanding that without my consent quotations will be anonymous and information that could identify me will not appear in this research paper or any subsequent publication. Information that could identify me includes, but is not limited to, my name, position title, department name, and the name of my organization.

I was informed that I may withdraw my consent without penalty by advising the researcher.

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. I was informed that if I have any comments or concerns resulting from my participation in this project, I may contact the Director, Office of Research Ethics at 519-888-4567 ext. 36005 or ssykes@uwaterloo.ca.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this project.

YES NO

I agree to have my interview audio recorded.

YES NO

I agree to the use of information that could identify me to be used in this research paper or any subsequent publication.

YES NO

I agree to the use of quotations in this research project

YES NO

I agree to the use of anonymous quotations in this research project and any publication that comes of this research.

YES NO

I agree to the use of direct quotations attributed to me only with my review and approval.

YES NO I agree to the use of direct quotations without my review and approval.

Participant Name: _____ (Please print)

Participant Signature: _____

Witness Name: _____ (Please print)

Witness Signature: _____

Date: _____