



A Review of Canadian Food Safety Policy and Its Effectiveness in Addressing Health Risks for Canadians

A Challenge Paper

Written by
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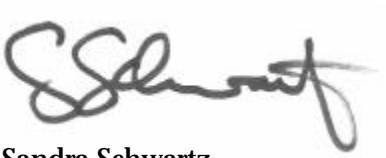
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Pollution Probe is pleased to release this commissioned paper on the food safety policy system in Canada. *A Review of Canadian Food Safety Policy and Its Effectiveness in Addressing Health Risks for Canadians* is the result of research and consultation over the past two years.

As a result of the highly polarized debate on food safety in Canada, along with the uncertainties surrounding non-traditional food safety risks, Pollution Probe believes that these areas require exploration and discussion. This challenge paper was commissioned by Pollution Probe as a means to inform the public on issues related to food safety in Canada.

The authors, Rod MacRae and James Alden, were given the charge of exploring challenges in the food safety policy system, with the goal of determining whether this system is effective in addressing existing and emerging food safety hazards. Their report is intended to identify issues and outline the health effects and policy linkages associated with the potential array of non-traditional food safety risks.

Canada has one of the safest food systems in the world; however, the rapid development of new food technologies requires continual examination of the concepts, framework and practices of food safety. Pollution Probe hopes that this paper will add value to the ongoing discussion on policy and regulatory decisions that are needed to protect the public from food-based hazards.

A handwritten signature in black ink, appearing to read 'S. Schwartz', is positioned to the left of a vertical line.

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Disclaimer

The contents and conclusions of this report are those of the authors and do not necessarily reflect the views and positions of either Pollution Probe or the expert reviewers.

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Executive Summary

The goal of this report is to examine the food safety policy system in Canada in order to determine whether it is effectively addressing existing and emerging food safety hazards. This in-depth and far-reaching analysis should be a valuable addition to the body of critical information needed to help make policy decisions that will better protect the public from food-based hazards.

Canada's food safety regulatory system is frequently described as the best in the world. There is a certain truth to that. Dramatic improvements in public health owe much to the sanitary measures put in place in the first part of the 20th century. Many well-understood microbiological hazards have been controlled and contained to a great extent. Looking at the history of some food-borne diseases, there's reason to claim that these are the safest of times.

However, in recent years, there has been an alarming increase in the incidence of diseases that may have causal links to food-based hazards. Major changes in the food and agricultural economy over the past several decades have made the food system much more complex. These changes have strained the ability of food safety systems to deal with well-characterized hazards, and have created new kinds of food safety threats.

The food safety regulatory apparatus has not kept up with these food system changes for a variety of reasons. The system relies on a risk assessment approach that cannot properly identify and address non-acute hazards — the kinds of hazards that have become more prevalent with changes to the food system. It does not properly weigh the benefits of

technologies that inadvertently generate hazards, or compare their performance to other approaches that might generate fewer hazards.

In addition, the lack of a prescriptive legislative framework means that implementation is subject to: budgetary pressures; staffing strategies within agencies; competing authorities among agencies; efforts to prevent political oversight of bureaucratic activity; and, bureaucratic difficulties sorting through conflicting policy directives, including those related to commercialization and trade.

In addition, it can be argued that the food safety apparatus has actually facilitated many of these destructive changes by imposing requirements on farmers and processors that favor larger, more centralized operations and by promoting trade and commercial interests over other considerations.

Governments have attempted to deal with new food system complexities by making minor modifications to the existing policy system and throwing more resources at problems. When this proved financially daunting in the era of cutbacks, governments started developing new frameworks for programme delivery, shifting responsibilities to the private sector, and changing the inspection process. It appears governments have been attempting to shift potential liability to the private sector as well. Responsibilities and agencies have been reorganized, legislation amended, and new systems for managing risks put in place. All these changes have effectively reinforced the dilemmas already facing the system. These problems are now

being played out in different ways, depending on the nature of the following categories of food safety hazards:

Traditional microbial pathogens —

For traditional microbial hazards (for which the current food policy system was largely structured), the implementation of Hazard Analysis Critical Control Point (HACCP) procedures has occurred in an environment of government down-sizing, deregulation, and liberalized trade agreements. Critics see HACCP procedures restricting the capacity of governments to exert authority over company activity, with attendant increases in food safety hazards.

Emerging pathogens — Many in the public health community are very concerned about the emergence of relatively new pathogens or the re-emergence of old ones thought to be under control. Numerous food-related, sociological and economic forces are thought to be responsible for this phenomenon, including: economic impoverishment, population migration, patterns of antibiotic use, immunosuppressing drugs, globalization of the food supply, travel, ecosystem destruction, crumbling public health infrastructure, and microbial adaptation. An emerging ecological theory is that as we see increased centralization and distance in the food system, there will be increases in the number of places for disease organisms to thrive. The food safety policy system is ill-equipped, at this point, to address the root causes of such problems, in part because it does not willingly examine how food system forces contribute to their spread.

Production technology hazards —

Conventional agriculture has become dependent on technologies and products (drugs, synthetic chemicals, plastics and, increasingly, genetic engineering) to

produce and distribute food. These technologies are increasingly understood to generate significant hazards. The three central features of the hazards in this category are that: (1) the technologies producing the hazard are assumed to be beneficial; (2) there are assumed to be no viable alternatives to these technologies; and (3) it is believed that any health risks associated with these technologies can be minimized by determining a safe level of application, residue or contamination (such as a tolerance or “no effect” level). However, determining levels of these materials at which no negative effect is likely is a highly contested process, producing both scientific controversy and trade disputes.

Food safety technology hazards —

In order to control pathogens, the food safety system has been promoting technologies that, themselves, may generate difficult-to-quantify hazards. Many additives are designed to extend shelf life, and to delay the process of food decay. Food decay, of course, can cause food safety problems. However, many additives are thought to have negative impacts on health. Food irradiation, which has limited application in Canada at this point, is also suspected of generating health hazards. These examples highlight how limited solutions produce unintended and unforeseen second-generation hazards.

Functional foods — The drive to develop functional foods is a market-driven response to consumer interest in nutritional health and the opportunities created by policy failure. Governments have failed to invest significantly in health promotion strategies that improve the nutritional health of the population. Instead, functional foods are developed and the regulatory system is not up to the task of properly assessing the hazards they might generate.

In summary, the current food safety policy apparatus is not up to the challenges posed by technological, economic and socio-cultural changes in the food system.

- For the most part, Canada's food policy does not deal with the root causes of food safety problems; instead it assumes that the way we produce and distribute food is fundamentally fine and that minimizing the spread of hazards (primarily through sanitation measures) will be sufficient.
- The science used to implement the policy is too limited and doesn't deal adequately with the uncertainty that results from the scientific enterprise.
- The policy system treats hazards differently when a technology that produces one is deemed beneficial; the risk/benefit assessment system is fundamentally flawed in numerous ways.
- The policy system is ecologically illiterate, so it fails to understand how hazards can be created and then spread.
- Human and financial resources are inappropriately allocated.

Many proposals to overhaul different components of the food safety system have been circulated. Commonly, they call for:

- a shift to root cause assessment;
- new ways to deal with scientific uncertainty, and systems designed around the precautionary principle (rather than the current risk assessment approach);
- changes to the benefit assessment process;
- changes to the human resource policies, so that the right people are in place to make the assessments, and they are provided with adequate resources; and,
- the separation of public health from commercial considerations, so that trade pressures do not compromise food safety.

To address all these significant challenges, the authors outline four broad initiatives for improving the food safety policy system:

1. establish a national food policy that has, as its paramount goal, the provision of nourishing, safe food;
2. incorporate the precautionary principle into Canada's regulatory framework;
3. carry out comparative technology assessments; and,
4. encourage the adoption of ecological farming systems that do not generate so many food safety hazards.

Preface

The current debate around food safety in Canada has become highly polarized. There are opposing opinions held on a wide range of questions related to the use of both existing and new technologies in the food industry. Among other issues, complex questions surround the production of genetically engineered foods, the use of pesticides and hormones in agriculture, and the use of irradiation and other technologies employed to preserve foods. The answers will not come easily. While on one hand, these technologies entail some level of risk for the general public, their use must be weighed against the success of the food production system in providing a wide and bountiful array of food choices.

Yet, despite the scientific and technological advances made in the production and distribution of food, hunger and malnutrition are still major threats to the health and well-being of millions of people all around the world. Every 3.6 seconds, someone in the world dies of hunger; three-quarters of these casualties are children.¹

Even those of us who enjoy the benefits of food security,² must still grapple with food-related health problems. The eating habits of westernized countries have changed dramatically over the past

decades. We are eating fewer home-cooked meals and more prepared and fast foods.³ For the first time in history, the number of overweight and obese people in the world is equal to the number of underweight and malnourished.⁴ This excess weight is associated with an increased incidence of cardiovascular disease, Type II diabetes mellitus, hypertension, stroke, hyperlipidemia, osteoarthritis, and some cancers. After smoking, obesity is the leading cause of preventable death in the United States.

In the last several years, Canadians have seen an alarming increase in the incidence of certain diseases that may have causal links to food-based hazards. Recent data reveal a marked increase in endocrine/nutritional/metabolic/immune (ENMI) disorders, thyroid disorders and hypertension. While some of the increased incidence of disease in these categories can be explained by lifestyle choices and an aging population, these diseases may also be linked to structural deficiencies in the food safety system that are contributing to food-based hazards.

increasingly suffer from hunger and malnutrition — even in Canada where more than two million Canadians use the services of over 450 food banks. <http://www.ryerson.ca/~foodsec>

³ Not only are prepared and fast foods often high in fat and low in nutritional value, they tend to contain additives and preservatives that may also pose health risks.

⁴ Recent estimates suggest that one-in-two adults in the United States is overweight or obese, defined by a body mass index (BMI) of higher than 25, an increase of more than 25 per cent over the past three decades (Must, A. et al, (1999), "The disease burden associated with overweight and obesity," *Journal of the American Medical Association*, 282 (16): 1523–1529).

¹ www.thehungersite.com

² 'Food security' as defined by the Ryerson Centre for Studies in Food Security, is "a condition in which all people at all times can acquire safe, nutritionally adequate and personally acceptable foods that are accessible in a manner that maintains human dignity." The Centre reports that despite the scientific and technological advances of modes of production and distribution, millions of people worldwide

While Canada has arguably one of the safer food systems in the world, the rapid development of new food production and processing technologies requires that we reassess the basic concepts, framework and practices of food safety. We must ask whether the existing food safety policy system in Canada is adequately protecting the public from any undue risks associated with food-based hazards? Or is it contributing to these risks?

The objective of this report is to examine the food safety policy system in Canada in order to determine whether it is effectively addressing existing and emerging food safety hazards. The authors recognize the development of a common vision around food safety will be difficult, but such a vision is required if we are to be successful in ensuring that Canada has the most healthful food system in the world. The authors believe this report will contribute to a greater understanding of the underlying and developing food safety issues and, in turn, help Canadians make informed policy decisions that will better protect the public from food-based hazards.

1. Introduction

Is the Canadian food safety policy system able to deal adequately with the range of food safety problems identified in this report? Is it properly structured to minimize the generation of, and exposure to, food safety hazards?

It is difficult to describe the Canadian food safety policy system succinctly:⁵ it is governed by many pieces of legislation;⁶ the federal, provincial and territorial governments carry out different or overlapping functions in a more or less coordinated fashion;⁷ and more than one agency may be operating within each jurisdiction, although certain ones tend to be central (for example, the Canadian Food Inspection Agency, federally). Numerous functions are carried out (training and education, pre-market consultations, product approvals and licensing, labeling and advertising, monitoring, inspection, post-market monitoring, recalls, enforcement, policy-making, import controls, etc.),⁸ with

multiple targets within the food production and distribution chain (including farms, processing plants, warehouses, retail, restaurants, imports and their foreign facilities), for a full and extensive range of food and packaging products.⁹

Canada's food safety regulatory system has been frequently described as the best in the world. There is a certain truth to that. Dramatic improvements in public health owe much to the sanitary measures put in place in the first part of the 20th century. Many well-understood microbiological hazards, such as botulism and brucellosis, have been addressed.

However, major changes in the food and agricultural economy over the past few decades have made the food system much more complex. These complexities have strained the ability of food safety systems to deal with well-characterized

⁵ To the authors' knowledge, a consolidated and detailed analysis of all the components and functions that comprise the Canadian food safety system currently does not exist. Due to the system's complexity, preparing such a consolidated analysis is a huge undertaking and beyond the scope of this report. The authors have attempted to outline the dominant themes of the food safety system without providing extensive detail on the mechanics of its operation.

⁶ The main relevant federal statutes include the *Food and Drugs Act*, *Canadian Food Inspection Agency Act* (Bill C-60), *Canadian Agricultural Products Act*, *Feeds Act*, *Fish Inspection Act*, *Seeds Act*, *Consumer Packaging and Labeling Act*, *Plant Protection Act*, *Plant Breeders Act*, *Health of Animals Act*, *Meat Inspection Act*, *Hazardous Products Act*, and the *Pest Control Products Act*. The provinces and territories also have enacted food safety legislation that covers food products that are not registered in the

federal system, and provides for oversight of food-related facilities that generally are not involved in inter-provincial trade (e.g., slaughtering plants that are not involved in inter-provincial or international trade) or that serve local markets (e.g., restaurants and food retail stores).

⁷ A new federal/provincial/territorial (FPT) framework for working on food safety was put in place in 1996. New elements of FPT collaboration are now being negotiated through the new Agricultural Policy Framework, announced in June 2002.

⁸ For an overview, see the CFIA web site <http://www.cfia-acia.agr.ca/english/index/fssae.shtml>.

⁹ For a summary overview of responsibilities, commodities covered, and pertinent pieces of legislation see Exhibit 25.1 of the 2000 Report of the Auditor General of Canada (<http://www.oag-bvg.gc.ca/domino/reports.nsf/html/0025xe01.html#0.2.MI3V39.I3SAEI.Z6BY4GL5>).

hazards, and have given rise to new kinds of food safety threats. The dominant food and agricultural economy is now characterized by the long-distance or global movement of goods, large-scale production and processing facilities, and the loss of smaller regional facilities. Many consumers have year-round access to previously seasonal foods and, as a result, have developed associated expectations of availability. In addition, there has been a recent emergence of new food products, including genetically engineered foods, functional foods¹⁰ and edible vaccines.¹¹ Traditional practices for mitigating bacterial contamination (such as salting, curing, canning, thermal processing, refrigeration and drying) have been replaced with more technologically-advanced processes, including the use of food additives, irradiation and, in some cases, genetic engineering.¹² The introduction of these new processes and technologies has been accompanied by new food safety risks. Finally, there are enormous financial pressures on farmers and small manufacturers that limit their capacity to implement food safety measures.

The speed at which these changes are taking place open new business opportunities; but with such opportunities come new risks — specifically, risks related to the safety of food products intended for the general public.

These changes may also be playing a role in the increase in the incidence of specific disease states. Disease data from IMS Health in Canada, a world-leading health information company, show startling disease trends that may have some link to some of the food-based hazards discussed in this report. Although the scientific evidence linking such diseases to food safety hazards is not definitive, in the view of the authors, it is sufficient to serve as an early warning of emerging food-borne phenomena to be explored and acted upon (see the appendices for further discussion).¹³

Particularly noteworthy is the increase in disease states related to endocrine and immune systems. Physician visits for endocrine/nutritional/metabolic/immune (ENMI) disorders surged a remarkable 55 per cent between 1996 and 1999. Much of the increase in ENMI disorders likely is due to a rapid increase in hyperlipidemia over the same period of time. High cholesterol levels are increasing among the general population, in part, because of North American diets that are heavy in saturated fats and cholesterol. Thyroid disorders increased 38 per cent over the three-year period. Much of this increase is related to improved testing equipment that can more accurately detect low-level glandular dysfunction, yet synthetic chemicals (such as organophosphate pesticides and

¹⁰ See Appendix F of this report for more information on functional foods.

¹¹ Note that not all these food products are regulated as foods under the Canadian system of genetic engineering (GE) regulation. Some are regulated as therapeutic products.

¹² For example, Bt-corn is often legitimized as a way to reduce the incidence of disease in corn.

¹³ The authors acknowledge that many experts contest a link between these disease states and food safety. In reviewing this report, several federal officials from Health Canada stated their belief that these diseases are more properly

categorized as related to food consumption and lifestyle choices. However, a significant body of public health literature contends that the role of lifestyle in disease conditions is generally overstated at the expense of systemic determinants of health status. Consistent with this literature, it is the experience of the authors that ascribing such problems to lifestyle choices distracts government officials from an examination of how their policies and programmes may be contributing to diseases and poor health.

Table 1: Fastest Growing Diseases With Possible Links to Food-Based Hazards

Fastest growing diagnosis classes, year 1999	Total number of diagnosis visits	% Increase since 1996
Total diagnosis visits	288,318,830	12.9%
Endocrine/Nutritional/Metabolic/Immune (ENMI) disorders	6,520,680	55.2%
Disease of thyroid	4,011,290	38.3%
Essential hypertension	16,280,240	27.8%
Neurological/Personality/Narcissistic personality disorders	22,715,400	26.5%

Source: IMS Health — *Canadian Disease and Therapeutic Index December 1999*

organochlorines) are known to target parts of the endocrine system, such as the thyroid gland.¹⁴ Pesticides may also play a role in suppressing immune system function. Finally, the contribution of animal production aids (for example, hormones) to endocrine system impairment has yet to be fully explored.

The food safety regulatory apparatus has not kept up with these rapid changes in the food and agricultural system; nor does it appear to be examining the potential connection between the increased incidence of some disease states and food-related hazards. In fact, it is argued by some that the food safety apparatus has facilitated these kinds of changes by imposing requirements on farmers and processors involved in trade that favor larger, more centralized operations. Governments have attempted to deal with new food system

complexities by making minor modifications and adding more resources. When this proved financially daunting in the era of cutbacks, governments started developing new frameworks for programme delivery, shifting responsibilities to the private sector, and changing the inspection process. It appears governments have been attempting to shift potential liability to the private sector as well. Responsibilities and agencies have been reorganized, legislation amended, and new systems for managing risks put in place. These system modifications have been made at a time when technological changes, new product approval needs, and the worldwide trade in food are at the highest levels ever.

Key to the new food safety system is the use of scientific risk assessment and a risk-based allocation of resources. This new approach has generated intense debates about desired levels of protection and about the appropriateness of different control measures, the scientific

¹⁴ Colburn, T. et al. 1997. *Our Stolen Future*. First Plume Publishing.

basis for risk decisions, public expectations, and the relative costs and benefits of intervention in different ways and in different components of the food system.

This paper explores in more detail the relationship between science, policy-making and regulation as it relates to food safety. Two central themes are explored: first, the failure to create a proper legislative framework for food safety has brought programmatic approaches to the forefront, particularly those using risk management; and,

second, governments have used a particular conception of risk, and have based risk assessment on a particular approach to scientific inquiry, in ways that limit the system's effectiveness. A related problem is that the food system is failing to recognize — in both policy and scientific terms — opportunities to reduce significantly the generation of hazards, so that the risks can be reduced or eliminated rather than managed. Building on these themes, some new ways to reduce food safety problems are proposed.

2. Categories of Food Safety Hazards

Food-related hazards are generated by different kinds of phenomena and the policy system, either explicitly or implicitly, treats them differently. The authors have identified five general categories of food safety hazards. Distinguishing among these categories is important if one is to examine the application of science and policy in the food safety system. These categories are:

1. the microbial and chemical food safety hazards the system has been designed to address historically (this includes such bacteria as *Salmonella* and *Listeria*, and certain heavy metals);
2. emerging pathogens that are likely a product of the design of the food and agricultural system, particularly intensive livestock operations and the globalization of distribution and processing;
3. hazards associated with technologies (and their by-products) that are commonly seen as central and beneficial to food production and distribution, including the use of pesticides, heavy metals, growth promotants, antibiotics, fertilizers, and genetically engineered crops and foods;
4. hazards associated with technologies introduced to solve other food safety and quality problems, including additives and irradiation; and,
5. hazards associated with new approaches to food as health delivery agents, functional foods and edible vaccines.

Historically, the Canadian food policy system has been designed to address, primarily, the first category of food-related hazards. The first category is distinguished from the other four for several reasons:

- The science of identifying acute disease hazards (and possible solutions) is more straightforward for microbial hazards; for many of the other categories, it is more difficult to identify clear cause-and-effect relationships, and negative impacts generally take longer to emerge. The degree of uncertainty is greater in examining hazards in categories 2–5 than in the first category.
- The solutions for the first category (such as improved sanitation, industrial design, etc.) are largely different from the solutions for the other four categories (which generally require food system redesign and the elimination of earlier generation solutions in favor of hazard prevention strategies).
- Pathogens (associated with the first category of hazards) are not beneficial, whereas many of the category 2–5 hazards (or the processes they're associated with) appear to provide some benefit.
- The hazards associated with the first category are generally regarded as “acts of nature”, whereas the others usually are considered products of human design.
- Comparing risks (and, therefore, allocating resources) is difficult enough within category 1, and

virtually impossible when comparing category 1 to the other categories.¹⁵ The Canadian Food Inspection Agency (CFIA) acknowledges that the ability to carry out such comparisons is in its infancy. In the authors' view, given the state of the science employed (see Section 3), it is impossible for such risk comparisons to be carried out.

In investigating an acute food-borne illness, such as *Salmonella*, it is a relatively straightforward process for toxicologists to establish a clear cause of illness or death. But toxicology, traditionally, has done a poor job in

establishing and quantifying the cumulative impacts on human health of consuming small amounts of potentially toxic substances over many years. Pesticides, food additives and hormones are tested more comprehensively for their short-term toxicity in high doses, than for long-term exposures at low doses, especially for the most sensitive growth stages of humans and other organisms.¹⁶

Each of these categories of food safety hazards are explored in more detail in this report (see Section 6), but first let's examine those problems common to all categories of food safety hazards.

¹⁵ Note that CFIA's project to address this has been shelved for lack of resources and appropriate models (see the 2000 Report of the Auditor General of Canada, <http://www.oag-bvg.gc.ca/domino/reports.nsf/html>).

¹⁶ For example, a review of the pesticide registration decision documents (PRDDs and RDDs) on the web site of the Pest Management Regulatory Agency (PMRA) reveals that many

decisions are taken without significant testing for developmental neurotoxicity associated with low-level exposure to infants of humans or other organisms. Application of additional safety factors to protect children is rarely applied, even when other data suggest such factors would be warranted. As well, many tests of chronic exposure to pesticides are not required when undertaking environmental assessments.

3. The Problems of Policy Science and Science-based Policy-making

The scientific assessment of hazard identification and risk management is the core of the current Canadian food policy system.¹⁷ The Network for Environmental Risk Assessment and Management (NERAM) defines risk management as “the means by which governments and other standard-setting organizations seek to define a rational level of acceptable or tolerable risk for an environmental hazard by considering the severity and probability of harmful health effects, the amount of environmental exposure experienced by human populations, the sources and means of control for the contaminant, and the expected costs and benefits of various risk reduction strategies.”¹⁸ Regulators and industry often describe the science employed to enable this process as “sound science.” The nature of this science is worth examining.

According to Salter and her co-authors who have studied the relationship between science and policy-making, “the science [policy-makers] seek is one that is capable of being justified and explained to a wide variety of publics.... It must

facilitate clear choices. It must represent a body of evidence on which decisions can rest and be seen to be rational.”¹⁹ One important aspect of this approach is that regulators attempt to minimize the likelihood of concluding there is an effect when one doesn’t exist, avoiding the possibility of “unnecessary” regulation (known in statistics as minimizing the possibility of a Type I error). However, this approach to regulation increases the likelihood of creating a different kind of error: the belief that there is no effect when one actually exists (or a Type II error).²⁰ The likelihood of a Type II error can be high; in some studies representing up to a 50 per cent possibility.²¹ Thus, there is a greater likelihood that policy-makers will claim that a risk doesn’t exist when it does, than the other way around.

This means policy-makers usually seek a high level of certainty before acting. But, “basing regulations on scientific data is not always clear-cut since it may take years before scientists generally agree about results of controversial studies.”²² Rather than deal with scientific ambiguity, regulators generally treat the absence of

¹⁷ A full description is not provided here. For an overview of a variety of risk assessment and management frameworks, see: Dyck, W. et al., *Current Directions in Environmental Risk Assessment and Management*, Network for Environmental Risk Assessment and Management (NERAM), February, 1999. Available at: www.neram.ca.

¹⁸ McColl, S. et al. 2000. *Environmental Health Risk Management: A Primer for Canadians*. NERAM, Institute for Risk Research, University of Waterloo, Waterloo, ON. <http://www.neram.ca/Pages/research/primer.htm>.

¹⁹ Salter, L. et al. 1988. *Mandated Science: Science and Scientists in the Making of Standards*.

Kluwer Academic Publishers, Boston, MA.

²⁰ Tickner, J. 1997. Precautionary Principle. *The Networker: The Newsletter of the Science and Environmental Health Net*. 2(4), May.

²¹ Schrecker, T. 1984. *The Political Economy of Environmental Hazards*. Law Reform Commission of Canada, Ottawa.

²² Congressional Research Service. RS20310: Science Behind the Regulation of Food Safety: Risk Assessment and the Precautionary Principle, Mickey Parish Congressional Science Fellow Domestic Social Policy Division Updated August 27, 1999. National Council for Science and the Environment, Washington.

evidence as evidence that there is no relationship. In this way, much of “policy science” is predicated on the assumption that if a phenomenon has yet to be observed, then it does not exist. With this approach, there is little room for the possibility that the effect has yet to be observed because we do not know how to “see” it.²³ Recent government documents suggest there is a growing recognition of the problem of uncertainty,²⁴ and show some cases where uncertainty has been well accounted for (including use of different statistical inferences).

However, it remains a common practice in food-related investigations for uncertainty to restrict the effectiveness of a risk assessment.

When properly resourced and implemented, the dominant risk assessments work reasonably well for assessing acute food safety risks, such as microbial contamination. However, they generally fall short when examining the chronic effects arising from long-term, low-dose exposures. Risk assessments in

this latter category often fail because of a lack of data, incomplete methodologies, and/or an inconsistent application across organizations and scenarios of the data and various methods that are available.²⁵ The practical implication is that when applying a risk assessment approach (and despite decision-making frameworks that suggest otherwise²⁶), regulators ultimately rank such things as drug and pesticide residues lower priorities than risks from microbial contaminants. Subsequently, because the science employed does not support a different decision, resources are allocated accordingly.

The decision to permit a product or process, based on the conclusions of a risk assessment that the attendant risks are manageable, is also susceptible to any value judgments imposed by policy-makers and regulators. For example, the decision to manage a risk is often made without even determining whether the purported benefits make that risk worth managing. This problem is discussed more fully in the following section of this report.

²³ MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219.

²⁴ See, for example, Health Canada, *Decision Making Framework for Identifying, Assessing and Managing Health Risks*. Aug. 1, 2000; and *A Canadian Perspective on the Precautionary Approach/Principle: Discussion Document*. Sept. 2001.

²⁵ For a more comprehensive critique, see Cooper, K. et al. 2000. *Environmental Standard Setting and Children's Health*. A Report by the Children's Health Project — a joint effort of the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee. May 2000.

²⁶ See, for example, Health Canada, *Decision Making Framework for Identifying, Assessing and Managing Health Risks*. Aug. 1, 2000.

4. The Failure to Assess Societal Benefits and Costs

Many hazards are associated with commodities and services that are thought to be essential to society. As a result, the decision is made to manage the hazard, rather than eliminate the source of the risk. However, this assumption of societal benefit is generally not tested because the food safety regulatory apparatus is not required to assess societal benefit.²⁷ The following remark by federal government officials, commenting on the potential licensing of genetically engineered recombinant bovine growth hormone (rBGH), illustrates this kind of assumption:

“The standard procedure in Canada and other industrialized countries is to regulate products based on scientific principles... Once safety and effectiveness have been reviewed, it is the marketplace in Canada which then decides on the market acceptance of the product, based on benefits such as price and individual values and preferences.”²⁸

This explains, in part, why the agricultural and processing practices, technologies and systems that may contribute to food safety hazards (categories 2–5) are not themselves scrutinized in identifying food safety

hazards. The Pest Management Regulatory Agency (PMRA), responsible for evaluating and licensing pesticides, does not evaluate whether society will benefit more from the licensing of a new product or from implementation of cultural practices that are part of an integrated pest management (IPM) framework. It determines only whether a new product is efficacious: whether it does effectively what the applicant claims.²⁹ Similarly, the Canadian Food Inspection Agency (CFIA), when assessing an application for the unconfined release of a genetically engineered (GE) crop, does not determine whether the technology will impose societal costs through, for example, economic losses at the farm level, or the need to repair any environmental damage associated with the technology. If an imported food product from a specific country consistently carries pathogens that are implicated in food-borne disease outbreaks, CFIA (consistent with government trade obligations) does not fully assess the societal merits of that product (for example, its healthfulness or its contribution to the Canadian economy). Consequently, the politics surrounding trade with that nation can be the most significant determinant of the speed with which an import restriction is put in place³⁰ (see section 5.3.1 for more discussion).

²⁷ Note that Health Canada's draft framework for decision-making, prepared as part of the transition of the health promotion infrastructure, suggests a fuller societal assessment process should be used (see Health Canada, *Decision Making Framework for Identifying, Assessing and Managing Health Risks*. Aug. 1, 2000). However, this philosophy has yet to penetrate the food

safety policy system.

²⁸ Government Response to the Report of the Standing Committee on Agriculture and Agri-Food, “rbST in Canada,” August 1994.

²⁹ See, PMRA. 1993. *Guidelines for Efficacy Assessment of Chemical Pesticides*. Regulatory Directive 93-07a.

³⁰ Perhaps the most significant assumptions

This systemic weakness becomes even more evident when the problem is generated by a system, not just by a practice or product. For example, although certain features of beef production are regulated (for example, the use of some drugs and production aids) and certain practices guided by what industry sees as “best practices” (such as manure management), the government department or agency has the explicit responsibility for evaluating whether the conventional system of beef production, implicated in the spread of *E. coli* 0157:H7 to the Walkerton water supply, generates these kinds of problems. This case raises consternation in the farm community (because the farm that was a possible source of contamination is seen to be well-

managed), shining a light on the deficiencies of the system itself (see Section 6 for more on this).

Certain kinds of economic risks are incorporated into the food safety system: economic risks associated with trading relations are factors in determining how resources are allocated (see pages 22 and 23); the economic risks of a potential hazard to a commodity sector may be taken into account; and the economic costs of various inspection options are considered. However, all these considerations are much narrower assessments than determining whether society benefits from a specific agricultural technology (and whether such benefits are worth the risk associated with the hazards it may generate).

surround the benefits derived from trade itself. Canada is deeply committed to an international trading regime. For an overview of the assumptions that drive this commitment, and their merits, see Toronto Food Policy Council. 1994. *Health, Wealth and the Environment: how the CUSTA, NAFTA and GATT impede the development of Canadian food security*. TFPC Discussion Paper #2, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

5. Legislative Weakness and Reliance on Regulation, Directives, Protocols and Programmes

In the Canadian tradition, legislation and inter-governmental agreements are normally broad and enabling,³¹ with the practical details provided in the regulations, directives, programmes, protocols and codes of practice promulgated under the statute or agreement. This approach is taken, in part, to facilitate adjustments to the statutory requirements without the necessity of parliamentary debate. Typically, major amendments to legislation require many years of discussion and consultation. However, the regulatory details are being changed all the time. In theory, such an approach is desirable because it allows political bodies to provide broad direction and oversight, and for civil servants to implement “the details” in a manner that is consistent with the political direction. It places a premium on an effective civil service that is properly resourced and accountable to the political process. This approach contrasts with other jurisdictions. The European Union is known for a more prescriptive approach, whereby legislation more specifically sets out performance requirements and thus

is less reliance on other instruments created at an administrative level to flesh out the intent of the legislation.

However, given the changing dynamics of governance in Canada,³² the theoretical advantages of the Canadian approach are not being fully realized in practice. The quality of “the details”³³ is now very influenced by: budgetary pressures, staffing strategies within agencies, competing authority between agencies, efforts to prevent political oversight of bureaucratic activity, bureaucratic difficulties sorting through conflicting policy directives (for example, facilitating commerce versus minimizing risk), the overall competence of the civil service, and the related reliance on the private sector for expertise (and consequently influence). The broad sweep of legislation also makes it more difficult for political bodies to determine and ensure programme and administrative compliance with the legislation. This explains, in part, the increased scope of audit functions carried out by the Auditor General and the use of Access to

³¹ The bulk of federal food safety legislation is derived from powers of criminal law (the *Food and Drugs Act*) or trade and commerce (e.g., *Canadian Agricultural Products Act* and *Meat Inspection Act*).

³² It is beyond the scope of this chapter to provide an overview; however, there is widespread concern about the increased authority of Cabinet over Parliament, the separation of bureaucratic from parliamentary activity, and the influence of the private sector in bureaucratic decision-making.

³³ Note, there are questions about the quality of enabling legislation. In his 2000 report, the Auditor General has questioned the legislative

authority to inspect certain imported foods. Although point-of-entry inspections of meat and fish are authorized under legislation, those foods covered under the *Food and Drugs Act* are not (unless subject to a special alert) and can only be inspected at the premises of the importer. Bill C-80 introduced in 1999 was designed, in part, to address this. The bill did not get beyond first reading, in part, due to controversial sections not related to these amendments. The bill is supposed to have been reworked and prepared again for introduction. Furthermore, the EU has questioned the authority of CFIA to carry out on-farm inspections of meat residue violations.

Information by civil society (the voluntary sector and the general public) to obtain information that might normally be presented as part of parliamentary committee processes. Some examples of how these themes are realized, relevant to food safety, follow.

5.1 Lack of Legislative Guidance Produces Weaknesses in Programme and Protocol Implementation

The European Union's Food and Veterinary Office, in their review of Canadian meat residue monitoring systems, concluded that:

“there is no specific legal provision in Canada on mandatory residue control programmes in food commodities of animal origin or live animals. There is only a general provision in paragraph 4d of the *Food and Drugs Act*, which provides that the sale of “adulterated food” is generally prohibited. Consequently, there are no legal provisions specifying which food commodities should be tested, which analytes are to be examined or the number of samples that are to be taken. All residue control activities are programme based, with the consequence that the scope and the extent of the programmes depend on the budget, which is allocated on a yearly basis.”³⁴

³⁴ European Union, Food and Veterinary Office. 2000. Final Report of a Mission Carried Out in Canada from 19 September to 29 September 2000 in *Order to Evaluate the Control of Residues in Live Animals and Animal Products*. DG (SANCO)/1188/2000 – MR final.

The Canadian view of its legislative approach is captured in the CFIA response to the EU report:

“The Canadian approach, although not similar from a legal perspective to the European Union's prescriptive preference, does provide for a comparable level of consumer protection.... The fact that Canada does not prescribe specific laws to deal with mandatory residue controls for food commodities of animal origin or live animals in no way limits authority to adequately respond to such a need. The fact that Canada has a very comprehensive and effective residue control program in place confirms this point.”³⁵

However, the EU inspectors found numerous critical examples of non-compliance with CFIA's own guidelines and protocols, suggesting that Canada's reliance on less prescriptive approaches leaves programmes subject to influences that legislation cannot override, leading to system failures. They concluded that the EU authorities should not be confident in residue claims made by Canadian authorities for meat exported to Europe.

Canada has no specific comprehensive legislation governing the regulation of GE products. Instead, they are evaluated through existing pieces of legislation, including the *Food and Drugs Act*, the *Feeds Act*, the *Fertilizers Act*, the *Seeds Act*, the *Plant Protection Act*, and the *Health of Animals Act*. These acts were adopted in

³⁵ <http://inspection.gc.ca/english/animal/meavia/eu/20001215eue.shtml>

much earlier regulatory eras, long before the application of modern genetic engineering to plants was envisaged. In fact, most of these statutes were written with the primary objective of preventing fraud,³⁶ or evaluating the agronomic, production or product quality parameters of the products under their jurisdiction. Only the *Canadian Environmental Protection Act (CEPA)* contains any references to the environmental and health aspects of biotechnology.³⁷ However, CEPA has only a limited impact on the current crop regulatory process, since other legislation is deemed to take precedence over it.³⁸ Evaluation of environmental or human health risks is not part of these statutes; hence, there is no clear legislative authority for the evaluation of GE crops or foods from an

environmental or human health perspective.³⁹ This deficient legislative framework allows regulators to set up data requirement systems that are primarily agronomic in nature, and not helpful for assessing environmental and health risks.⁴⁰ It allows space for regulatory concepts such as “familiarity and substantial equivalence” to be employed as decision thresholds in environmental and health assessment; these are concepts widely viewed as inadequate outside regulatory and industry circles.⁴¹ The precise nature of these data requirements and the data submitted to comply with them are not subject to public scrutiny, since they are part of processes considered administrative and commercial.

³⁶ Bjorkquist, S. and M. Winfield. 1999. *The Regulation of Agricultural Biotechnology in Canada*. Canadian Institute for Environmental Law and Policy, Toronto.

³⁷ CEPA provisions have been changed in the latest revisions to the act, revisions that significantly reduce legislative capacity to examine risk. For elaboration, see Bjorkquist, S. and M. Winfield, 1999, *The Regulation of Agricultural Biotechnology in Canada*, Canadian Institute for Environmental Law and Policy, Toronto. However, CEPA provisions are still sufficiently in force that a petition was filed May 9, 2000, by several environmental organizations with the Auditor General claiming that the federal government is violating CEPA (and other federal provisions) in the way in which it is regulating genetically engineered foods. The petition proposed a number of significant changes that must be made to the current system. Seven ministries responded without addressing, in a substantive way, any of the issues raised, and now the petitioners are examining options to contest the adequacy of the responses. See www.cielap.org for details.

³⁸ The federal government is currently going through the formal process of listing exempted legislation (e.g., the *Feeds Act*, the *Fertilizers Act*, the *Health of Animals Act* and the *Seeds Act*) under Schedule 4 of CEPA 1999 (where exempted legislation must be listed to prevent an environmental assessment of GE crops under

CEPA).

³⁹ Bjorkquist, S. and M. Winfield. 1999. *The Regulation of Agricultural Biotechnology in Canada*. Canadian Institute for Environmental Law and Policy, Toronto.

⁴⁰ Barrett, K. 1999. *Canadian Agricultural Biotechnology: risk assessment and the precautionary principle*. Ph.D. Dissertation, Department of Botany, University of British Columbia; Abergel, E. 2000. *Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada*. Ph.D. Dissertation. York University, Toronto; Clark, E.A. 2000. *Food Safety of GM Crops in Canada: toxicity and allergenicity*. Genetic Engineering Alert Canada. Available at www.canadians.org; Toronto Public Health. 2001.

⁴¹ Millstone, E. et al. 1999. Beyond substantial equivalence. *Nature* 401: 525–526. 1999; Barrett, K. and E. Abergel. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. *Science and Public Policy* 27: 2–12; An Expert Panel Report on the Future of Food Biotechnology prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. *Elements of Precaution: recommendations for the regulation of food biotechnology in Canada*. January 2001.

5.2 Budget Pressures Contribute to Human Resource Management Problems and Programme Weakness

5.2.1 *Problems in the Pest Management Regulatory Agency*

The Pest Management Regulatory Agency (PMRA) is responsible for regulating pesticides and implementing the *Pest Control Products Act* (PCPA). The PCPA has not been amended in a substantive way since 1969 and is viewed by critics to be significantly out-of-date. The Minister of Health introduced a new bill in March 2002 (Bill C-53, *Pest Control Products Act*), and it awaits passage through the Senate, having received 3rd reading in the House of Commons. How pesticide regulation in Canada fails to protect the most vulnerable members of the Canadian public (i.e., children) has been thoroughly analyzed in a report by the Canadian Environmental Law Association and the Ontario College of Family Physicians⁴² and need not be repeated here. Furthermore, the Parliamentary Standing Committee on Environment and Sustainable Development recommended a number of legislative changes to the way pesticides are evaluated and managed in Canada in their report *Pesticides — Making the Right Choice*.⁴³ Bill C-53, if adopted, will be an improvement over the old one, but only addresses a few of the concerns raised in these reports.

In the Canadian context, legislative improvements do not automatically

mean an overall improvement in food safety-related programming. As with other legislation, the PCPA sets out the broad framework for pesticide evaluation, with many of the application details relegated to directives, protocols and other data requirement procedures. The strength of these procedures and processes is determined by the quality of the civil service and the resources devoted to its work. For a number of years, these factors have been as significant as the weaknesses in the legislation in determining the slow pace of new pesticide registrations, particularly the registration of reduced risk-pesticides.⁴⁴ The following weaknesses in the pesticide evaluation and registration process are based upon interviews with key stakeholders who interact regularly with PMRA.

- The staffing strategy at PMRA has been a major impediment to quality-efficient reviews. The agency has been under-funded (although this situation appears to be shifting), which may explain, in part, the staffing strategy. A large percentage of the staff is on short-term contracts. The screening division positions have entry-level salaries that attract junior people, so most staff members are inexperienced in evaluation techniques. Many, once trained, immediately start looking for promotions to other sections of the government where employment is permanent and salaries higher. As a result, there is constant staff turnover.

⁴² For a full review, see Cooper, K. et al. 2000. *Environmental Standard Setting and Children's Health*. A report by the Children's Health Project — a joint effort of the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee. May 2000.

⁴³ Report of the Standing Committee on Environment and Sustainable Development

(2000). *Pesticide — Making the Right Choice for the Protection of Health and the Environment*, (available at: <http://www.parl.gc.ca/InfoComDoc/36/2/ENVI/Studies/Reports/envi01-e.html>).

⁴⁴ Associated with Bill C-53, the PMRA recently released a reduced risk regulatory directive that should also partly address delays in the registration of these products.

- Many of the senior evaluators have left because the work environment in the PMRA is far more constraining than the staff members' previous assignments. Management has done a poor job of integrating people from the various departments.
- The lack of experience means that evaluators are not really equipped with the knowledge or confidence to make good decisions. It's not necessarily that they don't have the right kinds of backgrounds, but they don't have the experience and confidence to make solid decisions. Consequently, there are frequently overly-literal interpretations of the protocols and data requirements, resulting in requests for additional work that otherwise might not be necessary. One of the results of this problem is the issuance of numerous temporary registrations because regulators are afraid of making full registrations.
- Part of the inexperience problem is that evaluators know little about agriculture, so they ask for information that is irrelevant or they don't properly recognize the significance of data.
- Decision-making protocols, although improved from earlier periods, are still deficient, particularly in the area of environmental impacts. If good, clearly elaborated protocols were in place, staff inexperience could be overcome.
- Senior managers have been unwilling to change the working procedures, the protocols and the evaluation process, even in the face of evidence that these instruments are not working

efficiently. Recent developments related to the Bill C-53 indicate this situation may be shifting.

5.2.2 *Problems in the Canadian Food Inspection Agency*

The Canadian Food Inspection Agency (CFIA) may be experiencing similar kinds of problems that impede successful implementation of numerous programmes. The agency's Human Resource Strategy⁴⁵ suggests that there are significant challenges associated with an aging staff complement, particularly within the inspection ranks, and with retaining qualified staff. Three key human resource management objectives have emerged in response.

1. **Maintain a qualified workforce:** the strategy acknowledges that new science skills are required, but also that employees will need skills and knowledge in other areas, such as communication, interpersonal skills, and mediation and conflict resolution.
2. **Attract and retain skilled employees:** the agency is anticipating problems with staffing gaps as a result of changing demographics,⁴⁶ unique skill set requirements, challenging working conditions and difficulties identifying suitable job candidates, particularly within the scientific community. CFIA recognizes that it is competing with other levels of government, private industry and

⁴⁵ CFIA. 2000. *Investing in Our Most Important Resource: Managing our People at CFIA: A Strategy 2000–2003*.

⁴⁶ Scientific, professional and technical employees account for 70 per cent, and in this category men outnumber women by 2:1. Almost half of all staff are aged 45 and above, and such a high percentage of employees nearing retirement presents a challenge.

other departments to access these skills.

3. Continue to build a supportive work environment: as a relatively new agency, there appears to be difficulties integrating staff from different backgrounds and histories. Given the kind of pressures the agency is under, staff morale is likely low.

The Auditor General's 2000 report on CFIA food safety systems shows that staff turnover has limited implementation of some key components of the food safety system. The AG's office "found that because of limited resources, the planned levels of activity were generally less than the levels required to deliver the programme as designed. We also found that actual levels of activity performed were lower than those that were planned. This suggests that either the required levels of effort are excessive or the levels of effort actually delivered are inadequate."⁴⁷ The federal government appears to have recognized this problem, and CFIA is in negotiations with Treasury Board about its long-term resources.⁴⁸

5.3 Food Safety Policies and Programmes are Subject to Commercial Pressures

Commercial considerations influence both the framework for, and the implementation of risk assessments within the Canadian food policy system. Commercial concerns underlie the very rationale for the policy framework and its management. In addition, the

capacity of private sector partners to carry out their part of risk assessment and management programmes is constrained by commercial pressures.

5.3.1 *The Impact of Liberalized Trade Policies*

It is clear that liberalized trade policies have been part of the impetus for moving away from a zero-risk to a managed-risk food policy system. A typical rationale is found in the CFIA Animal Health Risk Assessment Unit's justification for the creation of risk assessment frameworks:

"The animal health program historically was a semi-closed system in which the inputs, processes and outputs were relatively autonomous from their environment. The goal of import, for example, was zero-risk, and disease control activities centered around eradication.... In the early 1990s a risk assessment group was created to address the pressures of liberalized trade, farming of non-traditional species, the increase in disease intelligence and the need for transparent processes to arrive at decisions that minimize the risks."⁴⁹

In concrete terms, this framework has an impact on what gets monitored and what doesn't. Economic risk, associated with loss of trading relationships, is one of the factors that determine how resources are allocated. The economic value of imports rose 60 per cent between 1992 and 1998,

⁴⁷ See the 2000 Report of the Auditor General of Canada on CFIA, Chapter 25. <http://www.oag-bvq.gc.ca/domino/reports.nsf/html>.

⁴⁸ CFIA's response to the 2000 report of the Auditor General, contained within the body of the

report, <http://www.oag-bvq.gc.ca/domino/reports.nsf/html>.

⁴⁹ CFIA's web site: http://www.cfia-acia.agr.ca/english/ppc/science/ahra/docs/rasup_e.shtml.

reflecting significant increases in both trade and monitoring requirements. CFIA officials informed the Auditor General that the meat import programme is designed to manage both trade and food safety concerns, and so is resourced at a higher level than might seem appropriate. On the other hand, the import programme for commodities covered by the *Food and Drugs Act* is designed to manage only food safety concerns, even though many of these commodities are deemed to pose higher risks than raw meat imports.⁵⁰

5.3.2 Policy Obfuscation and Commercial Pressures

Commercial interactions with the policy system also generate policy obfuscation and confusion. Policy is created that deliberately or inadvertently facilitates commercial development of a technology at the expense of food safety. This happens at the framework level, at the level of decision thresholds, and at the level of consumer information rules. The policy design also tends to mask the commercial pressures.

At the framework level, the regulation of genetically engineered (GE) crops and food provides the starkest example. New crop varieties are assessed using a “safety-based” model that first requires a pre-regulatory review to determine if a risk assessment is required. Assessments are based on, primarily, submitted company data and the peer reviewed scientific

literature. There is no independent research carried out by regulators. A case-by-case approach is used which allows regulators and applicants some flexibility in the kinds of data that is submitted and reviewed. If a new product is found to be “substantially equivalent” and “familiar” to a conventional analog already approved by CFIA, then it will not require a further risk assessment. Commodity-specific guidelines help regulators determine if a novel product is substantially equivalent to those already approved.⁵¹ Applicants can and do use “substantial equivalence and familiarity” as the framework for presenting their data. Applicants draw a conclusion as to the familiarity and equivalence of their GE crop variety, and the regulators agree or disagree with the applicant’s assessment. Crops that are not deemed “substantially equivalent” undergo a risk assessment process. However, all applications to date have been deemed familiar and substantially equivalent and therefore no full risk assessments have been carried out.⁵²

Substantial equivalence and familiarity have been widely criticized as frameworks that facilitate commercialization, rather than assess safety based on good science. Several authors have examined the historical development of these regulatory concepts and the role of industry in determining their place in the policy arena.⁵³ Such approaches assume that the relationship between genetics, chemical composition, and toxicological and ecological risks are known, when in

⁵⁰ See the Auditor General’s 2000 report on CFIA at <http://www.oag-bvq.gc.ca/domino/reports.nsf/html>.⁵¹ Commodity specific reference documents have been developed for canola, corn, flax, soybean, potato, and wheat. However, other novel products have been approved for unconfined release for which no document has been posted.

⁵² For decision summaries, see CFIA’s web site at <http://www.cfia-acia.agr.ca/english/plaveg/pbo/ptchae.shtml>.

⁵³ Millstone, E. et al. 1999. Beyond substantial equivalence. *Nature* 401: 525–526; Barrett, K. and E. Abergel. 2000. Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada. *Science and Public Policy* 27: 2–12; Abergel, E. 2000. *Growing Uncertainty: the environmental risk assessment of genetically engineered herbicide tolerant canola in Canada*. Ph.D. Dissertation. York University, Toronto.

fact they are largely unknown. As well, the biochemical or toxicological effects of a GE food cannot be predicted from its chemical composition.⁵⁴

Seemingly minor changes in the molecular composition of a foodstuff can have significant nutritional implications. For example, a stereo-isomeric alteration to a non-genetically engineered molecule has been shown to have significant impacts on infant nutrition,⁵⁵ something that would not be revealed by a chemical composition analysis. If relationships are largely unknown, how can similarity in composition be a predictor of equivalent ecological or toxicological behavior as the regulators presume?⁵⁶ Another way of criticizing this regulatory assumption is to challenge the idea that single-gene changes resulting from genetic engineering necessarily result in well-characterized plant responses. In fact, single genes can affect many traits and produce unexpected phenotypic expressions.⁵⁷ Millstone et al.⁵⁸ provide two current examples of how single gene changes produce unpredictable outcomes: experimental genetic manipulation of oilseed crops, including

canola, has led to the unexpected discovery of changes to lipid metabolism; and, glyphosate tolerance in Roundup Ready soybeans appears to occur at the expense of diminished heat tolerance due to changes to the plant's lignin content.⁵⁹ If the responses are often unpredictable, then substantial equivalence has no merit as a trigger for environmental assessments. The Expert Panel of the Royal Society of Canada is particularly critical of the use of substantial equivalence as a decision threshold — the determination of whether a full risk assessment is required — and proposes that it be abandoned as a determination approach.⁶⁰

Drug approvals with food implications, such as recombinant bovine growth hormone (rBGH), have been subject to questionable managerial contradictions of data interpretations by bench scientists. In the rBGH case, it was clear that managers within Health Canada shared, at a minimum, a similar worldview with industry.⁶¹ At worst, they saw themselves facilitating the commercialization of a drug with limited data to support its approval.⁶² Approval

⁵⁴ See CIELAP's report *A Citizen's Guide to Biotechnology* at <http://www.cielap.org/citizensbiotech.pdf>.

⁵⁵ Medical Research Council (UK). 2000. *Report of a MRC Expert Group on Genetically Modified (GM) Foods*. June 2000.

⁵⁶ Millstone, E., et al. 1999. Beyond substantial equivalence. *Nature* 401: 525–526.

⁵⁷ Bergelson, J. and C.B. Purrington. 1994. *Reviewing the cost of resistance in plants and its relevance to biotechnology risk assessment*.

⁵⁸ Millstone, E. et al. 1999. Seeking clarity in the debate over the safety of GM foods. December 9. *Nature* 402, 575 (1999) (Reply to letters to the editor).

⁵⁹ This is thought to occur because the insertion of the glyphosate-resistant EPSPS in these varieties alters product distribution in the shikimate pathway that leads to the creation of aromatic amino acids, lignin, some vitamins and other secondary metabolites. See Gertz, J.M. et

al. 1999. *Tolerance of transgenic soybean (Glycine mar) to heat stress*. 1999 Brighton crop protection conference: weeds. Proceedings of an international conference, Brighton, UK, 15–18 November 1999, Volume 3, 835–840.

⁶⁰ An Expert Panel Report on the Future of Food Biotechnology Prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada. 2001. *Elements of Precaution: recommendations for the regulation of food biotechnology in Canada*. January 2001.

⁶¹ This was revealed in Health Canada's rBGH Gaps Analysis report (see TFPC. 1997. *Recombinant Bovine Growth Hormone*. TFPC Discussion Paper #9, Toronto; and TFPC. 2000. *The Canadian Regulatory Process for Evaluating Recombinant Bovine Growth Hormone in the Dairy Industry: a critical review*. TFPC Discussion Paper #10, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm), ATI requests

for rBGH was not given (based on a January 1999 announcement), but only after Health Canada was forced by the controversy over managerial behavior to solicit outside opinion on the merits on the drug.

Food irradiation has also been a controversial technology (see Appendix D). It is regulated as a food process under the *Food and Drugs Act* and its regulations, which prevents irradiation (and the controversial radiolytic compounds it creates) from being subject to the intensive scrutiny normally given to chemical contaminants and additives.⁶³ Unless one considers the commercial interests brought to bear, regulators appear to be inconsistent in their application of the regulations. With genetic engineering, only the end-product is regulated, not the process that creates it. With food irradiation, however, the process is regulated, not the irradiated foods that result. These contrary approaches do not make sense unless the objective is to reduce testing and facilitate commercialization.

Consumer information related to food irradiation is also confusing in two significant ways. First, the visual symbol (the radura) looks like a growing plant benefiting from radiant sunshine. Given the potential for food quality degradation during irradiation, such a symbol poorly reflects the process itself. Secondly, only

those food ingredients constituting 10 per cent by weight or more of the processed product need be identified as irradiated on the label. Although irradiation is permitted to be used on potatoes, onions, wheat, flour and whole wheat flour, and spices, its use is primarily restricted to spices. However, spices rarely, if ever, comprise 10 per cent of a processed food product; therefore, consumers are largely unaware of the irradiation of the spices present in many processed foods. Such rules permit the use of irradiation technology to be hidden; given widespread consumer opposition to the technology, this policy better suits commercial than public interests.

5.3.3 Private Sector Implementation

The current food policy system relies heavily on effective implementation at the farm, feedlot and processor level. There is evidence that many private sector partners do not follow directives and guidelines, either deliberately or because of a lack of resources or information.⁶⁴ Failure to comply may not be uncovered by authorities unless an overt problem results, since monitoring systems rely extensively on notification from the private sector. Such reliance may be reasonable in situations where firms have a major incentive to notify (for example, a food-borne illness outbreak that most food manufacturers

and submissions to the Senate Committee on Agriculture for its hearing on recombinant Bovine Growth Hormone (1998).

⁶² See the Toronto Food Policy Council (TFPC) reports on this subject. TFPC. 1997. *Recombinant Bovine Growth Hormone*. TFPC Discussion Paper #9, Toronto; and TFPC. 2000. *The Canadian Regulatory Process for Evaluating Recombinant Bovine Growth Hormone in the Dairy Industry: a critical review*. TFPC Discussion Paper #10, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

⁶³ Food irradiation was regulated as an additive in the US, which led to much more extensive scrutiny of the end-product.

⁶⁴ The magnitude of this problem is difficult to ascertain because it is not information willingly provided. Formal surveys generally miss such things. It is usually from inspection reports (e.g., EU residue monitoring report) and anecdotal information (e.g., what farmers and manufacturers reveal during informal discussions) that shines a light on these problems.

greatly fear for its short and long-term economic consequences⁶⁵). However, self-reporting is problematic when it concerns non-acute hazards related to the use of drug and production aid residues, pesticides, and genetically engineered crops and foods.

Many experts outside industry and government view the numbers of samples taken in drug and pesticide residue programmes as inadequate.⁶⁶ The lack of good data is even more pronounced for GE foods. There is no effective post-release monitoring programme for GE foodstuffs, since CFIA and Health Canada rely on genetic engineering firms and the scientific literature to warn them of potential problems. There is not even a direct way to survey post-consumption health impacts, since GE foods are usually not labeled.⁶⁷ Since there are almost no empirical data on the health impacts of GE food diets,⁶⁸ firms only track changes to genetic constructs in crops and foods.⁶⁹ Health Canada has launched a Biotechnology Surveillance Project to address the problems of post-release monitoring.⁷⁰ While welcome, this initiative highlights the perverse logic of the current regulatory system: regulators are approving for release GE products whose post-release impacts they poorly understand and have little capacity to evaluate.

5.3.4 Risk Management Systems Create Consequences That May Not Be Intended Within Established Legislative Frameworks

Canadian food safety policies have a complex influence on the scale of food producing, processing and distribution operations. Large firms (and farms) have more resources to implement programmes, such as the Hazard Analysis Critical Control Point (HACCP) system,⁷¹ than do most small firms. It is, in fact, one of the criticisms of the new approaches to food safety that they favor large operations over small ones and are contributing to the process of consolidation within the food and agricultural sector (as small operators are forced out of business and their resources directly or indirectly acquired by better resourced operations). Following interviews with farmers and microprocessors, the Toronto Food Policy Council⁷² came to the conclusions, set forth below, on how the food safety system constrains small operators.

- It is expensive to meet food safety regulations and most are designed for large operations.
- Inspectors often do not provide technical assistance and expect operators to have the sophisticated knowledge (and the associated

⁶⁵ When surveying food company marketing managers in 1997, the Toronto Food Policy Council found that this was a priority worry. See TFPC. 1998. *Consumers are Sovereign: how to change food information systems so food shoppers are the informed consumers governments and businesses say they should be*. TFPC Discussion Paper #8, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

⁶⁶ European Union, Food and Veterinary Office. 2000. Final Report of a Mission Carried Out in Canada from 19 September to 29 September 2000 in Order to Evaluate the Control of Residues in Live Animals and Animal Products. DG (SANCO)

/1188/2000 — MR final; pesticide reference.

⁶⁷ For more on this, see Toronto Public Health. 2001. *Genetically Engineered Foods*. City of Toronto, Toronto. April.

⁶⁸ Domingo, J.L. 2000. Health risks of GM foods: many opinions but few data. *Science* 288 (June): 1748–1749.

⁶⁹ Monsanto notified regulators of unexpected gene constructs in some of their Roundup Ready soybean lines. These constructs were not deemed to be significant by regulators.

⁷⁰ http://www.hc-sc.gc.ca/pphb-dgspsp/csc-ccs/biotech_e.html#DoingNow; <http://www.gmfoodsurveillance.org/>

formal education) needed to meet the regulatory requirements. Inspectors often do not see themselves as problem solvers.

- It is difficult to test market products until a fully approved facility is in place. Yet, small operators usually cannot afford to put everything in place before developing a test market for their product. Facilities that can address this problem (such as food technology centers and incubator kitchens) are only available in a limited number of communities.

Favoring large operators over small ones may ultimately prove to be self-defeating in food safety terms. An emerging theory⁷³ says that larger firms operating in a liberalized trading environment and effectively implementing programmes like HACCP reduce the likelihood of a small-scale food-borne illness outbreak (relative to small firms), since they have more money to effectively implement programmes.

However, because of their size, the volume of food flowing through their plants, and their global sourcing and distribution, if there is a problem, it is more likely to have widespread consequences than if a problem emerges in a small plant that serves a primarily local or regional market. Food-borne disease outbreaks associated with liberalized trade frequently have national and international implications, do not follow the patterns of earlier outbreaks, and require enormous resources to track food movements and identify those made ill.⁷⁴

A related problem (although risk assessment theory suggests otherwise) is that regulators do not treat low-likelihood events with limited consequences any differently than they treat low-likelihood events with major consequences. As an example, many health and ecological consequences of GE technology fall into this category of low-likelihood events with major consequences.⁷⁵ However, the emphasis of the assessment is shifted

⁷¹ According to CFIA, the Hazard Analysis Critical Control Point (HACCP) System is “one of the tools that industry and government are using to produce safe food.... This system was first designed and used in the 1960s to ensure safe food for astronauts in the US space programme. HACCP is based on detecting and preventing problems in food products during their production. This scientific system is now being used worldwide by the food industry to produce safe food for all consumers. CFIA is strongly committed to implementing HACCP and HACCP-based inspection programmes and is currently implementing the following HACCP food inspection programmes: the Food Safety Enhancement Program (FSEP) (voluntary for federally-registered establishments under the *Meat Inspection Act* and the *Canada Agricultural Product Act*); and the Quality Management Program (QMP) (mandatory for federally-registered fish processing establishments).” Note, revisions are now underway to make HACCP implementation mandatory in registered facilities under the *Meat Inspection Act*.

⁷² Toronto Food Policy Council. 1995. *Stories of Food Microenterprises and Implications for*

Community Economic Development. TFPC Discussion Paper #5, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

⁷³ Well articulated in Waltner-Toews, D. 1992. *Food, Sex and Salmonella*. NC Press, Toronto.

⁷⁴ Tauxe, R. 1997. Emerging Food borne Diseases: an evolving public health challenge. *Emerging Infectious Diseases* 3(4): 425–434.

⁷⁵ For example, antibiotic resistance gene transfer from Bt-corn to bacteria in the guts of animals is considered by some to be a one-in-a-million event (see Centre for Food Safety University of Guelph backgrounder “GM plants and antibiotic marker genes” (1999), www.plant.uoguelph.ca/safefood/index.htm). However, the consequences for treatment of human diseases are significant, as we know already from recent experience with agriculturally-generated antibiotic-resistant bacteria. Given that there are billions of corn seeds produced annually with antibiotic-resistant marker genes, fed to millions of cows, with billions of bacteria in their stomachs, a one-in-a-million event is no longer such a low likelihood. A number of studies carried out for the UK Food Standards Agency suggest that such gene

much more towards the likelihood of a risk being generated than on its consequences. There are two primary reasons for this. The first relates to the reliance on the dominant scientific tradition, known as positivist-reductionist science.⁷⁶ This scientific approach has little predictive power, since inquiry focuses on specific phenomena that have been isolated from their ecological context, and is not usually sufficiently multidisciplinary to capture systems' effects. This kind of science favors outcomes of no effect, especially when dealing with complex ecological phenomena. The second reason is that the regulatory system does not have an explicit cost assessment function (see Section 4). There is no rigorous evaluation of the potential societal costs of implementing a technology; consequently, only the most obvious negative costs (already widely

known or resulting obviously in significant mortalities) receive consideration. Although there is little evidence that action is being taken to deal with this situation, CFIA seems to have some appreciation of the problem. Senior CFIA official Bob Clarke was cited as telling the Canadian Grains Commission that the complexity of the food system has made it more vulnerable. He stated, "when something goes wrong, because of the rapid dissemination and transportation that we have, a very small incident can turn into a major problem in a very short period."⁷⁷

It seems unlikely that legislators intended such impacts when developing Canada's food safety legislation. However, such unintended effects are, in part, the consequence of structural flaws in our food policies and the associated pressures that result from those flaws.

transfer events are possible, both in vitro and in vivo (http://www.foodstandards.gov.uk/science/sciencetopics/gmfoods/gm_reports).

⁷⁶ For a review of how this approach to science limits inquiry about ecological phenomena in agriculture, see MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219.

⁷⁶ For a review of how this approach to science limits inquiry about ecological phenomena in agriculture, see MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219.

⁷⁷ Rance, L. 2001. Food system safe but complacency makes it vulnerable. *Manitoba Cooperator* April 19, 2001. p.6.

6. Examining the Five Categories of Food Safety Hazards

Category #1: The Microbial and Chemical Food Safety Hazards the System has been Designed to Address Historically

Much of the basic policy infrastructure for the food safety system was put in place in the late 19th and early 20th century, and has been linked with the commercial movement of food. This link with commerce has always complicated efforts to protect and ensure public health. This inherent conflict of interests remains today; although, as trade patterns and intensity have changed, the nature of the problem has shifted somewhat.

The first food safety regulation emerged in an 1875 amendment to the *Inland Revenue Act*, imposing duties on alcoholic beverages and prohibiting the adulteration of food, drink and drugs. The federal government set up laboratories, staffed with analytical chemists, which monitored the contents of goods moving around the country (the Food and Drug Directorate). This effort proved successful in reducing levels of adulteration and fraud, the preliminary focus of food safety efforts at that time.⁷⁸

In the early part of the 20th century, more attention was paid to disease. The *Meat and Canned Food Act* (later the *Meat Inspection Act*), for example, was first

adopted in 1907 and was designed to address one of the primary concerns of the day — the transmission of diseases from animals to humans. Disease, however, was much more difficult to test for than adulteration, so the system of visual inspection that has been central to food safety for most of the past 70 years came to dominate food safety procedures. Visual inspection also worked better in a trading environment, since product shipments would not be delayed by sampling or the wait for test results.⁷⁹

However, the ability of visual inspection to detect many types and levels of microbial contamination has been questioned⁸⁰ (a concern that has, in part, driven interest in HACCP models). In addition, industry had been complaining for several decades that inspection requirements suffer from duplicated and inefficient government services, and result in excessive costs imposed on industry.⁸¹ Although the shift to HACCP has changed the focus from primarily endpoint inspections to designing preventive processes, its implementation has also been subject to trade pressures. The transformation has occurred in an environment of government downsizing, deregulation, and liberalized trade agreements, and critics see HACCP restricting the capacity of governments to exert authority over company activities.⁸²

⁷⁸ McKinley, W.P. 1980. Food Safety in Canada: past present and future. *Association of Official Analytical Chemist* 63 (2): 158–162.

⁷⁹ Note that current approaches to testing have also failed on this matter, in that goods have not been held pending testing results; when problems emerge, regulators have relied on “post-release” recalls.

⁸⁰ See, for example, Ehiri, J.E. and G.P. Morris. 1995. HACCP implementation in food business: the need for a flexible approach. *Journal of the Royal Society of Health* 115(2): 249–253.

⁸¹ Brown-John, C.L. 1986. Reforms in regulatory processes affecting Canada’s food industry. *Food Policy* 11: 345–357.

⁸² See, for example, Leonard, R. 1996. Stealth

Similar to the introduction of genetic engineering, “sound science” claims have been used to justify the model, even though it has been implemented without the data needed to support claims of greater effectiveness than previous approaches.⁸³ This has reinforced the belief that its implementation is driven primarily by trade pressures.

Outbreaks of *Cyclospora* infection in Canada and the US illustrate how trade pressures can affect policy systems designed to control microbial contaminants.⁸⁴ *Cyclospora* is a parasite and, until recently, most people infected with it in North America were travelers recently returned from the developing world. In the mid-1990s, however, a series of outbreaks were ultimately traced to consumption of raspberries imported from Guatemala in the spring months. These tracebacks were complex because of the difficulties of detecting *Cyclospora*, particularly in raspberries with their rough surfaces and extensive cilia. Following outbreaks in 1996, a HACCP system was introduced to the Guatemalan raspberry industry, with an agreement within the industry that only low risk farms would be eligible to export to North America. Despite implementation of HACCP, outbreaks continued in 1997. In 1998, the US did not permit raspberries to be imported for the spring period, but Canada did. In fact, it was not until after a significant outbreak occurred in the spring of 1998 in Ontario, that CFIA took any import control action, restricting the farms from which the raspberries could come. The Guatemalan

government voluntarily decided to cease exports.

These outbreaks resulted in hundreds of illnesses and hospitalizations, associated work time losses and health care system costs, and significant costs to the public health system that carried out the outbreak investigation. Contrast this with the benefits of importing and eating Guatemalan raspberries in spring. They do not provide a nutritional benefit that cannot be obtained from other sources, and the economic benefits would be limited to a few importers. Despite this, CFIA did not put import controls on the product until late spring 1998, and rebuffed requests from partners in the outbreak investigation to do so, even after the raspberries were identified as the likely source. In fact, a lawyer acting for CFIA intimidated Toronto Public Health officials over their efforts to inform the public that Guatemalan raspberries were the likely source of the parasite.⁸⁵ Although the official explanation from CFIA was that there was insufficient evidence to link the outbreak to the raspberries, partners in the outbreak investigation believed the evidence was sufficient, and the resistance was due to CFIA’s role in trade promotion.⁸⁶

HACCP and related food safety measures may prove to be useful tools in preventing microbial contamination, but it is currently compromised by the long-standing tension in the food safety policy system between trade and public health.

politics replaces public debate on policy. *Nutrition Weekly*. January 19, 1996. pp. 4–5.

⁸³ Leonard, R. 1996. HACCP is not a Science-based system. *CNI Weekly* May 10; 4–5.

⁸⁴ Basrur, S. 1998. *Cyclospora outbreak in spring 1998*. Toronto Board of Health. October 30, 1998.

⁸⁵ Smith, J. 2001. Preventing public health tragedies. *Toronto Star* May 11, 2001. A21.

⁸⁶ The lead author was employed by Toronto Public Health at the time and participated in discussions about the outbreak.

Category #2: Emerging Pathogens that are Likely a Product of the Design of the Food and Agricultural System, Particularly Intensive Livestock Operations and the Globalization of Distribution and Processing

Many in the public health community are very concerned about the emergence of relatively new pathogens or the re-emergence of old ones thought to be under control⁸⁷ (see Appendix A). Numerous food-related, sociological and economic forces are thought to be responsible for this, including: economic impoverishment, population migration, patterns of antibiotic use, immunosuppressing drugs, globalization of the food supply, travel, ecosystem destruction, crumbling public health infrastructure, and microbial adaptation.⁸⁸

An emerging ecological theory is that with increased centralization and transport distances in the food system, there will be increases in the number of places for disease organisms to thrive.⁸⁹ The food safety policy system is ill-equipped at this point to address the root causes of such problems, in part, because it does not willingly examine how food system forces contribute to their spread.

For example, hamburger disease — *Escherichia coli* 0157:H7 — appeared in

industrialized countries in the mid-1980s. A “new” pathogenic strain (0157:H7), at least at the molecular level, of a well-known bacterium (*E. coli*), shows how the industrialization/centralization of the food system contributes to the emergence of new and old pathogens. Outbreaks have been associated with ground beef, raw milk, lettuce, and both minimally-processed and fresh fruit juices.

The contraction of the *E. coli* 0157:H7 bacteria poses serious risks to human health. The tragedy in Walkerton, Ontario in early 2000, demonstrated the virulent nature of the *E. coli* 0157:H7 bacteria. Hundreds fell ill, and there were a number of deaths due to a complication called hemolytic uremic syndrome (see Appendix A). Even today, many of the survivors are forced to live with compromised kidney function resulting from this bacterium.

E. coli 0157:H7 lives in cattle. It is likely that the emergence of this strain is the result of changes in the way beef cattle are raised and slaughtered, and ground beef prepared for sale.⁹⁰ Feeding cattle a diet primarily of grain may be a factor because it creates acid conditions in the stomach that favour 0157:H7 over competing bacteria.⁹¹ The increased use of uncomposted manure slurries to fertilize pastures — often required because the farm has too many animals and manure

⁸⁷ See, for example, Toronto Board of Health 1996. *Emerging and re-emerging Infectious Diseases*. City Clerk, Toronto. May 27, 1996; Toronto Board of Health. 1997. *Is Food the Next Public Health Challenge?* City Clerk, Toronto, Aug. 1997. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

⁸⁸ CDC. 1994. *Addressing emerging infectious disease threats: a prevention strategy for the United States*. Executive Summary. MMWR 1994; 43 (RR5): 1–18.

⁸⁹ Waltner-Toews, D. *Food, Sex and Salmonella*. NC Press, Toronto.

⁹⁰ For an overview, see Armstrong, G.L. et al. 1996. Emerging food borne pathogens: *Escherichia coli* 0157:H7 as a model entry of a new pathogen into the food supply of the developed world. *Epidemiol Rev* 18(1): 29–51.

⁹¹ There is some debate about this. A Cornell University study found that animals fed a grain rather than hay-based diet shed higher levels of *E. coli* 0157:H7 (Couzin, J., 1998. Cattle diet

storage facilities are overflowing — may have played a role in the increased contamination, as *E. coli* 0157:H7 can grow in manure. There have been cases of infection resulting from consumption of produce grown in fields fertilized with cattle manure.

Unfortunately, the new high volume, industrial slaughtering processes mean that most animals are starved before slaughter. The digestive activity of a well-fed cow inhibits the growth of bad bacteria in the stomach. But the animals are not usually fed during shipment to the slaughtering plant, and animals with empty stomachs are easier to slaughter.

A third suspect industrial practice is a change in ground beef production. Ground beef is mass-produced. The meat from several cows may go into one hamburger patty. Large commercial packers may purchase meat from different sources all over the world. The grinding machinery is used continuously without cleaning between lots. Once sent to grocers, it is re-ground, and trimmed fat from more expensive cuts often added. In the end, one contaminated animal could infect thousands of hamburgers, all because of the demands of industrial processing.

Solving this problem requires a full re-examination of the beef production, processing and distribution system. However, federal food safety agencies do not have the authority, tools or expertise to conduct an investigation of this magnitude. There is no history of regulating on-farm feeding practices in Canada, and any attempts to do so would

be viewed as infringements upon private property and commercial rights. Provincial and federal governments, collaborating with farm organizations and universities, have relied on a combination of research, extension, voluntary programmes, and market forces to guide farmer practices. Such activities have not been traditionally associated with food safety divisions within governments, and the interagency and even interdivisional collaboration required to use these traditional tools to address the problem is not at an advanced stage of development. There are signs this may now shift with the implementation of the new Agricultural Policy Framework, announced in June 2002.⁹²

Similarly, Canadian governments have chosen largely not to oppose industry consolidation and increasing scale of operation,⁹³ except in limited cases that demonstrate a loss of competitiveness or obvious environmental hazard. Consequently, there is no process to examine how the scale of a slaughtering facility might contribute to this problem, and whether scale restrictions to balance commercial and food safety interests might be appropriate. These are admittedly complex questions requiring sophisticated institutional arrangements and policy and programme tools. Rather than engage in discussions of this nature, at least part of the food safety establishment continues to propose food irradiation of beef as the solution. Beef is permitted to be irradiated in the US, but not in Canada. But irradiation creates its own hazards, which are discussed further under category 4.

linked to bacterial growth. *Science* 281: 1578–1579). Other studies have not come to this conclusion.

⁹² For more on this new policy framework, see http://www.agr.gc.ca/cb/apf/index_e.html.

⁹³ See, for example, Winson, A. 1992. *The Intimate Commodity: food and the development of the agro-industrial complex in Canada*. Garamond Press, Toronto.

Category #3: Hazards Arising from Technologies (and Their By-products) that are Commonly seen as Central and Beneficial to Food Production and Distribution

Conventional agriculture is dependent on drugs, synthetic chemicals, plastics and, increasingly, on genetic engineering to produce and distribute food. The three central features of our food policy system that contribute to the creation of the hazards in this category are that: (1) the technologies producing the hazard are assumed to be beneficial; (2) there are assumed to be no viable alternatives to these technologies; and, (3) it is believed that any health risks associated with these technologies can be minimized by determining a safe level of application, residue or contamination (such as a tolerance level or a “no effect” level).

The capacity of such technologies to improve the quantity or quality of the food supply is largely assumed on faith by the regulatory apparatus (since the relevant agencies have no prescribed role to determine whether such benefits actually exist). The agricultural policy apparatus beyond the food safety system does not necessarily assume such benefits, but relies extensively on published literature (if it exists) that tends to reinforce the dominant view of the technology. For example, it is axiomatic that synthetic pesticides and fertilizers are essential to food production, yet the economic literature on which such conclusions are based contains many major, and untenable, assumptions. Economists have claimed

that synthetic nitrogen fertilization (N-fertilization) provides high levels of economic return per dollar invested. But this analysis assumes that N-fertilization need not be compared fully to other fertilization strategies, and the associated benefits of these strategies are discounted from N-fertilizers. When this kind of analysis is provided, financial returns from N-fertilization do not appear to be much more favourable than other strategies such as green manuring, rotations and the use of animal manures.⁹⁴

In a similar vein, James provides an indication of the overestimation of economic returns from the application of pesticides.⁹⁵ He compared the traditional valuation of returns from granular carbofuran use in western Canadian canola seed production (since banned) with the insect control losses associated with the carbofuran-induced deaths of insectivorous birds. He concluded that in many cases, carbofuran contributed to a net loss of pest control efficacy. Typically, studies on pesticide restrictions do not take account of the other pest management practices put in place to manage pests and the environmental and health benefits that can result.⁹⁶

In other cases, like crop genetic engineering, there is little empirical economic literature to support industry and regulatory claims that the technology produces significant societal benefits that warrant (what they believe to be) a low level of attendant risk.⁹⁷ Even at the farm level, evidence of financial benefit is contradictory at best. Claims of higher

⁹⁴ See for example, Caldwell, V.B. 1982. Fifty years of Minnesota corn production: sources of yield increase. *Agronomy J.* 74: 984–990.

⁹⁵ James, P.C. 1995. Internalizing externalities: granular carbofuran use on rapeseed in Canada. *Ecological Economics* 13: 181–184.

⁹⁶ Jaenicke, E. 1997. *The Myths and Realities of*

Pesticide Reduction. Policy Studies Report #8. Henry A. Wallace Institute for Alternative Agriculture. Washington, DC.

⁹⁷ See CIELAP's report *A Citizen's Guide to Biotechnology* at <http://www.cielap.org/citizensbiotech.pdf>.

yields have not been realized across the board, varying by region of North America, commodity and study. HT⁹⁸ soybean yields in the US are usually lower than comparable non-GE varieties.⁹⁹ Yields of Bt-corn¹⁰⁰ and cotton have been very variable by US region.¹⁰¹ Two studies on canola produced conflicting results: one identified no consistent yield advantage for GE canola,¹⁰² while the other did.¹⁰³ From the evidence compiled to date, the consistent theme is that GE crops only outperform conventional varieties under particular circumstances (e.g., for Bt-corn, under conditions of high European corn borer pressure).

CFIA agrees that many of these GE crops only perform well under stressful conditions.¹⁰⁴ This raises an interesting question. If GE crops only perform well under specific conditions, why are regulators approving them as if they are universally useful? If the benefits are limited, shouldn't that shift the framework for risk assessment? There is no requirement to entertain such a consideration.

Determining levels of these materials at which no negative effect is likely is a highly contested process. The debate is perhaps most advanced in the approval and regulation of pesticides¹⁰⁵ (see Appendix B) and animal production hormones (see Appendix C), where it continues to generate both scientific controversy and trade disputes. It is necessary to identify a no-effect level to legitimize the use of the technology, and, consequently, governments spend millions of dollars evaluating industry applications to commercialize them.

Setting tolerance levels for bacterial contaminants is different than setting them for chemicals. In contrast to most chemical contaminants, extremely low levels of some bacteria can cause acute disease symptoms in humans (for example, *E. coli* 0157:H7). As a result, the regulatory view is that it is not possible to set tolerances for some bacteria in some products since no effective microbiological monitoring is feasible.¹⁰⁶ The strategy in these cases is preventive — how can the likelihood of contamination be minimized? The problem is more complex

⁹⁸ HT-soybeans are herbicide tolerant soybeans that contain a genetic modification that makes the crop tolerant of a herbicide that used to kill it.

⁹⁹ Benbrook, C. 2001. *Troubled Times Amid Commercial Success for Roundup Ready Soybeans: Glyphosate Efficacy is Slipping and Unstable Transgene Expression Erodes Plant Defenses and Yields* Northwest Science and Environmental Policy Center, Sandpoint Idaho. May 3, 2001; Ervin, D.E. et al. 2000. *Transgenic crops: an environmental assessment*. Winrock International, Baltimore, MD.

¹⁰⁰ Klotz-Ingram, C. et al. 1999. Farm level production effects related to the adoption of genetically modified cotton for pest management. *AgBioForum* 2(1): 24–32. Available at www.agbioforum.org/archives.htm.

¹⁰¹ A Bt (*Bacillus thuringiensis*) crop has gene sequences from this bacterium inserted in it to kill certain insect pests.

¹⁰² AAFC. 2000. Lethbridge Research Centre

Report. *Benefits of HT Canola systems vary, system shows*. Jan. 13, 2000. <http://res2.agr.ca/lethbridge/rep0113.htm>.

¹⁰³ As reported by growers in a survey conducted by Serecon Management Consulting Inc. and Koch Paul Associates. 2001. *An Agronomic and Economic Assessment of Transgenic Canola*. Prepared for the Canola Council of Canada. January 2001.

¹⁰⁴ Dr. John Larsen, CFIA. Personal communication. March 13, 2000.

¹⁰⁵ Cooper, K. et al. 2000. *Environmental Standard Setting and Children's Health*. A report by the Children's Health Project — a joint effort of the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee. May 2000.

¹⁰⁶ Bacteriological guidelines are published, however, for fish and fish products, meat and meat products.

when the negative impact results from secondary effects of a technology, as occurs with antibiotic-resistant bacteria. Regulators currently have no comprehensive preventive approach in place.

Using antibiotics as performance enhancers has been criticized as only being effective for animals kept in overly crowded, unsanitary conditions. According to this view, antibiotic use has facilitated excessively intensive animal husbandry practices and could be avoided by the observance of good animal care practices.¹⁰⁷ Others have said that the use of antibiotics in agriculture has contributed to a rise in the virulence of food-borne pathogens and has impeded their treatment and the control of their spread.¹⁰⁸

At this point, there is no programme in place to monitor systematically for resistant pathogens, despite evidence that certain production systems (such as turkey farms) have significant levels in tested flocks. The authors of one study concluded that *Salmonella* are resistant to many, mostly older, antibiotics used in the turkey industry. They studied 270 turkey flocks in 1994 and found *Salmonella* resistance to neomycin in 14 per cent of samples, resistance to spectinomycin in 97.6 per cent, to ampicillin in 14.3 per cent, to sulfamethoxazole in 58.1 per cent, and to tetracycline in 38 per cent. The authors also speculate that resistance may soon develop to some of the newer drugs being used, with an attendant potential to compromise medical treatment.¹⁰⁹ There are calls to ban sub-therapeutic antibiotic use in animal feed

because there does not appear to be a level of antibiotic administration at which resistance will not occur.

Category #4: Hazards Arising from Technologies Introduced to Solve Other Food Safety and Quality Problems

As discussed above, some technologies that are used to solve potential food safety problems may potentially create additional problems. Many additives are designed to extend shelf life, and to delay the process of food decay. Food decay, of course, can cause food safety problems. However, as discussed in Appendix E, many additives are thought to have negative impacts on health. Food irradiation, which has limited application in Canada at this point, is also suspected of generating health hazards (see Appendix D).

These examples highlight how limited solutions may produce unintended and unforeseen second-generation hazards. Typically, the first generation “solutions” are the product of commercial science, the wedding of science with commercial interests. The food and agricultural sector has a long history of seeking solutions to problems with marketable products — commodities or processes that can be bought and sold in the marketplace. Such solutions are not based on a full understanding of the phenomenon and the forces that create or contribute to the creation of the hazard. Typically, they do not entail the redesign of the processes or systems that have created the problem,

¹⁰⁷ Addison, J.B. 1984. Antibiotics in sediments and run-off waters from feedlots. *Residue Rev.* 92: 1–28.

¹⁰⁸ Nolan, L.K. et al. 1991. Comparison of phenotypic characteristics of *Salmonella spp* isolated from healthy and ill (infected) chickens.

Am J Vet Res 52(9): 1512–1517.

¹⁰⁹ Dr. Cornelius Poppe, Agriculture and Agri-food Canada. Personal communication. Sept. 20, 1995. Poppe, C. et al. 1995. Drug resistance and biochemical characteristics of *Salmonella* from turkeys. *Can J Vet Res* 59: 241–248.

in part, because such redesign would require a more complete knowledge base and often does not produce a technology that someone has to purchase to solve their problem.¹¹⁰

While the risks of irradiated foods are unclear, policy decisions in Canada and the US are reflective of the food industry's desire to expand this technical process. In February 2000, the US adopted a new federal rule allowing for the irradiation of raw beef, pork and lamb in order to reduce microbial contamination. While these new rules may help protect the public from food contamination, they raise serious questions about the industrial farming practices that helped produce the hazard and now require the technical fix.

A second feature of this category of hazard is the compartmentalization of phenomena, allowing regulators to treat second-generation problems associated with a technology as insignificant. Promoters of food irradiation acknowledge the second-generation problems (see Appendix D) and admit that irradiation leads to a three to ten per cent decline in vitamins and minerals, and that it creates new carcinogenic chemicals in foods. They just don't think that these changes are significant.¹¹¹

Apparently, regulators agree, despite the fact that *Food and Drug Act* regulations state that companies must provide:

“... (d) data indicating the effects, if any, on the nutritional quality of the food, raw and ready-to-serve, under the proposed conditions of irradiation and any other processes that are combined with the irradiation; (e) data establishing that the irradiated food has not been significantly altered in chemical, physical or microbiological characteristics to render the food unfit for human consumption.”¹¹²

If there were no other phenomena reducing the nutritional value of food or contaminating the food supply, then such events might not be significant. But there is already significant food contamination (including pesticide residues, antibiotic residues, heavy metals, hormone and drug residues, and industrial contaminants introduced through atmospheric deposition¹¹³), as well as evidence of nutrient decline associated with many different phenomena, including plant breeding,¹¹⁴ poor soil management,¹¹⁵ harvest date,¹¹⁶ storage and long-distance food transport,¹¹⁷ food processing,¹¹⁸ and

¹¹⁰ MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219.

¹¹¹ Strauss, S. 1998. Save stomachs: zap food, Canada advised. *G&M* June 17, 1998.

¹¹² *Food and Drugs Act* Regulations B.26.005.

¹¹³ See Mausberg, B. and P. Muldoon. 1999. *A Taste of Canada*. CELA, Toronto.

¹¹⁴ Doyle, J. 1985. *Altered Harvest*. Viking Press, New York.

¹¹⁵ Woese, K. et al., 1997. A Comparison of Organically and Conventionally Grown Foods — Results of a Review of the Relevant Literature.

Journal of the Science of Food and Agriculture 74: 281–293. Velimirov, A. et al. 1992. The influence of biologically and conventionally cultivated food on the fertility of rates. *Biological Agriculture and Horticulture* 8: 325–337. Knorr, D. and H. Vogtmann. 1983. *Quality and Quality Determination of Ecologically Grown Foods in “Sustainable Food Systems”* ed. by Knorr, D. Westport, CT: AVI Publ. Co., pp. 352–381.

¹¹⁶ Shewfelt, J. 1990. Sources of variation in the nutrient content of agricultural commodities from the farm to the consumer. *J. Food Quality* 13:37–54.

¹¹⁷ Klein, B.P. 1987. “Nutritional consequences of minimal processing of fruits and vegetables”, *J. Food Quality* 10: 179–193.

losses in one's refrigerator.¹¹⁹ Conceivably, onions bred to increase yield and disease resistance could be grown on a farm with depleted soil in California, be irradiated in storage, spend a week in transit from farm to Canadian processing plant, end up in a jar of French onion soup, and then sit in a fridge for three weeks. The nutrient decline would be dramatic. And this wouldn't just be happening in onions. Evidence from USDA¹²⁰ and MAFF¹²¹ historical nutrient files shows that the content of some minerals in fresh vegetables has declined some 60 to 80 per cent over 30 and 50-year periods, respectively. Similar kinds of results were found in Canadian data sets released by Health Canada.¹²² Because of the compartmentalization of decision-making within regulatory agencies, no one has the responsibility for tracking the aggregated impacts of different technologies on food quality.

Category #5: Hazards Arising from New Approaches to Food as a Health Delivery Agent

The broad context for the development of functional foods centers on a fundamental failure in health policy — because governments are failing to improve health determinants and general population health, they are consequently

relying on technological solutions to produce drugs and food constituents with reputed health benefits¹²³ (see Appendix F). It is widely accepted that adequate nourishment is essential for normal growth and development, reproductive health, maximum work output, optimal mental functioning, the ability to concentrate and learn, physical stamina, and a feeling of well-being.¹²⁴ Appropriate nutrition is also essential for the prevention of disease. The link between nutrients and disease began with the identification of diseases caused by nutrient deficiencies (and the curing of these diseases by eating foods containing those nutrients). Nutrient deficiencies are no longer widespread health problems. Now, the major public health challenges are posed by such chronic diseases and conditions as cardiovascular disease, hypertension, stress, cancer, diabetes, low birth weight infants, obesity and anaemia, all of which are associated with more subtle forms of inadequate nutrition.¹²⁵

In particular, excess fat intake and/or insufficient consumption of fibre, fruits and vegetables are linked with such diseases. In fact, the 1988 US Surgeon General's Report on Nutrition and Health stated that: "the evidence suggests strongly that a dietary pattern that contains excessive intake of foods high in

¹¹⁸ Gussow, J.D. and K.L. Clancy. 1986. Dietary guidelines for sustainability. *J. Nutrition Education* 18(1): 1–5.

¹¹⁹ Klein, B.P. 1987. "Nutritional consequences of minimal processing of fruits and vegetables", *J. Food Quality* 10: 179–193.

¹²⁰ Bergner, P. 1997. *Healing Power of Minerals, Special Nutrients and Trace Elements*. Prima Publishing, Rocklin, CA.

¹²¹ Marie-Mayer, A. 1997. Historical changes in the mineral content of fruits and vegetables: a cause for concern? In: Lockeretz, W. (Ed). *Agricultural Production and Nutrition: proceedings of a conference*. Tufts University. pp. 69–77.

¹²² Obtained by Avis Favaro of CTV News and

reported in a series of reports on CTV and in the *Globe and Mail*, June 2002.

¹²³ Although nutrition is not usually considered part of the food safety framework, the potential for nutrition strategies to generate food safety hazards would be, which is why the authors have chosen to include this discussion.

¹²⁴ Spasoff, R.A. 1987. *Health For All Ontario. Report of the Panel on Health Goals for Ontario*. Queen's Printer, Toronto; Surgeon General (US). 1988. Report on Nutrition and Health. US Department of Health and Human Services, Public Health Service, Washington, DC.

¹²⁵ Health and Welfare Canada. 1988. *Promoting Healthy Weights: a discussion paper*, Minister of

calories, fat (especially saturated fat), cholesterol, and sodium, but that is low in complex carbohydrates and fibre, is one that contributes significantly to the high rates of major chronic diseases among Americans.” Moreover, it estimated that 71 per cent of deaths, including more than one-third of cancer deaths, fall into disease categories that have strong associations with diet.

The numbers of people at risk due to poor diet and food insecurity is high. According to the 1992 *Ontario Health Survey*, 75 per cent of the population exceeds recommended dietary intake of fat. Over half the population does not consume recommended levels of vegetables, and over two-thirds fail to consume recommended levels of grains. Children, as well as adults, are more obese, less active and less healthy.¹²⁶ In addition, lower income people are less likely than higher income people to consume a nutritionally optimal diet.¹²⁷ Up to 25 per cent of Metro Toronto residents may not have sufficient income to afford a nourishing diet.¹²⁸

The chronic diseases mentioned above also account for the majority of our health care costs. Health Canada has

concluded that the economic burden associated with unhealthy eating for just coronary heart disease, stroke, diabetes and cancer is \$6.3 billion annually, including \$1.8 billion in direct health care costs and \$4.4 billion in indirect costs (such as indirect health care expenditures, productivity losses, etc.).¹²⁹ This is an underestimate as it represents the costs related to only four diet-related diseases.

Given the scale of the problem and the factors involved in creating nutritional health, a comprehensive policy and programme effort is required. Unfortunately, investment in good nutrition by the federal and provincial governments remains very low.¹³⁰ Rather than addressing population dietary patterns and the quality of the food supply provided by the food industry,¹³¹ significant investments in “nutraceuticals” are on the horizon.

Nutraceuticals are natural, bioactive chemical compounds that have health promoting, disease preventing or medicinal properties. There are currently no specific regulations dealing with nutraceuticals or functional foods (foods which contain nutraceuticals), although

Supply and Services Canada, Ottawa; Surgeon General (US). 1988. Report on Nutrition and Health; US Department of Health and Human Services, Public Health Service, Washington, DC.

¹²⁶ A Toronto Star article reported that the prevalence of obesity in Canadian kids aged 7 to 13 has more than doubled between 1981 and 1996 (Toronto Star, May 30, 2000).

¹²⁷ James, W. et al. 1997. The contribution of nutrition to inequalities in health. *BMJ* 24 (May): 314: 1545–1549.

¹²⁸ Toronto Department of Public Health. 1997. *Is Food the Next Public Health Challenge?* Toronto Board of Health, Toronto. September 5, 1997. http://www.city.toronto.on.ca/health/ufpc_discussion_paper.htm.

¹²⁹ The assumptions are that improved diets could reduce coronary heart disease and stroke

mortality by at least 20 per cent, and cancer and diabetes mortality by at least 30 per cent. The Canadian cost estimates came from Moore et al. 1997. *Economic Burden of Illness in Canada 1993*. Health Canada, Ottawa. http://www.hc-sc.gc.ca/hpb/lcdc/publicat/burden/burd4_e.html.

¹³⁰ Precise estimates are hard to come by since nutrition programming is often co-mingled with other lifestyle programmes, but it is not likely more than 1/10 of one per cent of total health care spending.

¹³¹ The ways food production and distribution in a globalized food economy reduce the nutritional status of populations is a large and complex topic. The World Health Organization is concerned about this phenomenon and has created a project, Nutrition in Transition, to investigate it. See <http://www.who.int/nut/trans.htm>.

they are in development.¹³² All foods and drugs fall under the provisions of the *Food and Drugs Act* (FDA) and its regulations. Those functional food applications that are a result of genetic engineering fall under the Novel Food Regulations, implemented under the authority of the FDA. Problems of GE regulation discussed in other sections of this paper are relevant to the development of GE nutraceuticals. For nutraceuticals, the key regulatory dilemma for government lies in the definitions of foods and drugs (sections 3 and 5 of the FDA). Since companies want to make claims about the health and therapeutic advantages of their nutraceutical products, the government is under pressure (and is now considering) how to amend the rules regarding health claims, since under current rules such claims would mostly likely change the nutraceutical's category from food to drug with the attendant additional requirements for testing and regulation.¹³³ According to a government discussion paper on the subject:

“The claims that can be made for a food without changing its regulatory status are limited to nutrient content claims, claims referring to Canada's *Guidelines for Healthy Eating* (1992) and nutrient function (biological role) claims. Present requirements for drugs (manufacturing GMPs, marketing restrictions, Quality Control procedures) are perceived as difficult for most

food products to meet and therefore very few manufacturers have applied for and been granted a Drug Identification Number (DIN) for food products. Furthermore, food producers want to avoid the perception of their product being a drug. Also, Section 3 of the *Food and Drugs Act* precludes claims made directly to the public for the cure, prevention or treatment of any of the diseases or abnormal physical conditions listed in Schedule A to the Act, conditions which many food manufacturers wish to directly address.”¹³⁴

Significant resources within Health Canada and Agriculture and Agri-Food Canada (AAFC) are now being allocated to sort out these dilemmas, with the interest driven largely by the commercial opportunities that may result for farmers and the agri-food sector. Regulators seem prepared to accept the claim that since some emerging evidence on nutraceuticals/functional foods suggests they can have a positive impact on some individuals, that this can be translated into significant improvements in the nutritional health status of the population. Yet, there is no evidence that a policy and programme investment in such an approach will generate positive population-wide outcomes. Rather than increase investments in comprehensive population-based and targeted strategies to improve the nutritional health of the population,¹³⁵ regulators are at least

¹³² See, for example, proposed regulations regarding health claims, http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_reg_proposal_eng.html.

¹³³ For more on what options the government is weighing, see http://www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/

[chronology_of_events.html](http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_reg_proposal_eng.html), and <http://www.agr.ca/food/nff/enutraceutical.html> (AAFC).

¹³⁴ Health Canada. 1997. *Policy Options Analysis: nutraceuticals/functional foods*. http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/ffn/polyopts_e.html.

¹³⁵ For an overview of the types of programmes

indirectly shifting resources to a market-based approach with no evidence that it will be successful. Given the factors that determine nutritional health, there is no reason to be optimistic it will. And since some hazards could emerge from

nutraceuticals, particularly if a product of genetic engineering (see Appendix F and the earlier discussion about the limitations of the GE regulatory system), investing in nutraceuticals seems entirely premature.

that should be considered, see Toronto Food Policy Council. 1997. *If the Health Care System Believed You Are What You Eat*. TFPC Discussion Paper #3. TFPC, Toronto. http://www.city.toronto.on.ca/health/tfpc_discussion_paper.htm.

7. What's To Be Done?

In summary, Canada's current food safety policy apparatus is not up to the challenges posed by technological, economic and socio-cultural changes in the food system.

- For the most part, the policy apparatus does not deal with the root causes of food safety problems. Instead, it assumes that the way we produce and distribute food is fundamentally fine and that minimizing the spread of hazards (primarily through sanitation measures) will be sufficient.
- The science used to determine policy is too limited and that policy doesn't adequately deal with the uncertainty that results from the scientific enterprise.
- The risk/benefit assessment system is fundamentally flawed in numerous ways. The policy system treats a hazard differently when a technology that produces one is deemed beneficial.
- The policy system is ecologically illiterate, so it fails to understand how hazards can be created and then spread.
- Human and financial resources are inappropriately allocated.

Paradoxically, the system relies extensively on private sector involvement to deliver an effective system. Part of the motivation for this has been the recognition that, in a liberalized trading world, the expense of ensuring food safety would be significantly higher than in a more

restricted or regional food production and distribution system. But the complexity of global food trade (and of a less prescriptive food safety system) means that food safety is now fundamentally unmanageable. The will, competence and resources do not exist to make it work properly. The stark reality is that governments will have to either invest significantly more resources in a major overhaul of the food safety system, withdraw to some degree from global food commerce, or live with the additional public health expenses associated with a food safety system that permits and even generates ill health.

Given the extensive challenges facing the food safety system outlined in this report, some major redesign is in order. Although this redesign must ultimately extend to the most fundamental foundations of the system — for example, the design and implementation of scientific studies and the protocols used by government staff to evaluate and act upon potential and known hazards — there are some broad frameworks, processes, and policies that must first be put in place in order to make detailed redesigns effective. Critics of food safety systems have proposed several systemic amendments, including:

- a shift to root cause assessment;
- new ways to deal with scientific uncertainty, and systems designed around the precautionary principle (rather than the current risk assessment approach);
- changes to the benefit assessment process;

- changes to human resource policies, so that the right people are in place to make the assessments and they are provided with adequate resources; and,
- the separation of public health from commercial considerations so that trade pressures do not compromise food safety.

In addition, the authors of this report outline four fundamental policies and processes that they believe must be put in place to improve the food safety policy system:

1. establish a national food policy that has, as its paramount goal, the provision of nourishing, safe food;
2. incorporate the precautionary principle into Canada's regulatory framework;
3. carry out comparative technology assessments; and,
4. encourage the adoption of ecological farming systems that do not generate so many food safety hazards.

Each of these recommendations is discussed in some detail below.

7.1 Establish a National Food Policy that has, as its Paramount Goal, the Provision of Nourishing, Safe Food

Canada does not have a national food policy. It has policies that address some of the components, particularly agriculture, but nothing that sets a clear policy direction to nourish the population with safe food. Although the mission statements of individual ministry programmes (such as those

operated by Health Canada¹³⁶) suggest otherwise, when the activities of all government departments are taken into account, nutrition and safety are clearly subservient to market and trade objectives. According to Agriculture and Agri-food Canada, the Canadian food and agricultural system is to be:

“A growing, competitive, market-oriented agriculture and agri-food industry that is profitable and responds to the changing food and non-food needs of domestic and international customers; is less dependent on government support; and contributes to the well-being of all Canadians and the quality of life of rural communities, while achieving farm financial security, environmental sustainability and a safe, high quality food supply.”¹³⁷

Attempts to create a national food policy in the 1970s failed, largely due to opposition from Agriculture Canada, which saw the move as a threat to its jurisdiction and traditional clients.¹³⁸ But the effort must be made again, and a

¹³⁶ For example, according to Health Canada staff, the mission of the Food Program is to protect and improve the health of the people of Canada through science-based policies and programmes related to safe and nutritious food.

¹³⁷ Agriculture and Agri-food Canada (AAFC). 1994. *Future Directions For Canadian Agriculture and Agri-food: a vision of growth through security, security through growth, creating the balance*. AAFC, Ottawa.

¹³⁸ MacRae, R.J. 1999. This thing called food: policy failure in the Canadian food and agriculture system. In: M. Koc, R.J. MacRae, L. Meugeot and J. Welsh (eds.). *For Hunger-proof Cities: Sustainable Urban Food Systems*. International Development Research Centre and the Ryerson Centre for Studies in Food Security. Ottawa. pp. 182–194.

comprehensive food policy should have the following dimensions:

- Everyone has enough food (both in terms of quality and quantity) to be healthy.
- Food production, processing and consumption are suited to the environmental, economic, technological and cultural needs, potentials and limits of the distinct regions of Canada.
- The food system is recognized as providing an essential service. Food supply and quality are dependable. They are not threatened by social, political, economic and environmental changes.
- Food is safe for the people who produce it, work with it and eat it, and it is also safe for the environment.
- Resources (energy, water, soil, genetic resources, forests, fish, wildlife) are used efficiently (in an ecological sense), and there is no waste.
- The resources of the food system are distributed in a way that ensures that those who provide the most essential tasks are provided a decent income. In particular, people in rural communities have enough work and income to maintain or improve their life, and to care for the rural environment.
- Flexibility exists to allow for improvements and adaptation to changing conditions.
- Everyone who wants to be involved in determining how the food system works has a chance to participate.

- Opportunities are available for creative and fulfilling work and social interaction.
- The food system functions in a way that allows other countries to develop food systems with similar values.¹³⁹

7.2 Incorporate the Precautionary Principle into Canada's Regulatory Framework

Although the precautionary principle is described in CEPA, it currently has little bearing on the design of the Canadian food safety regulatory system. The precautionary principle first emerged in Germany in the 1970s. As Joel Tickner articulates, "at the center of the precautionary principle is the concept of taking anticipatory action in the absence of complete proof of harm, particularly when there is scientific uncertainty about causal links."¹⁴⁰

The principle is already an operational part of the European regulatory framework. For its genetic engineering regulation, the European Community enacted the Deliberate Release Directive 90/220 in 1990. According to Levidow et al.:

"... this legislation was precautionary, because it was designed to prevent hazards not yet documented for [genetically-

¹³⁹ MacRae, R.J. 1999. This thing called food: policy failure in the Canadian food and agriculture system. In: M. Koc, R.J. MacRae, L. Meugeot and J. Welsh (eds.). *For Hunger-proof Cities: Sustainable Urban Food Systems*. International Development Research Centre and the Ryerson Centre for Studies in Food Security. Ottawa. pp. 182–194.

¹⁴⁰ Tickner, J. 1997. Precautionary principle. *The Networker: The Newsletter of the Science and Environmental Health Network*. 2(4), May.

modified organisms] GMOs. It was based on a qualitative uncertainty about cause-effect models of harm, rather than upon 'risk' as a quantifiable harm ... It provided a framework for clarifying uncertainty about risk — or rather, about potential effects that might constitute or lead to environmental harm."¹⁴¹

The Directive was also designed to harmonize EU-wide procedures and criteria for market approval of products (although its success has been mixed because it vaguely defined too many significant terms and principles over which member states could debate). Given that the principle is already operational in Europe, the gap between principle and practice is not so great as many Canadian officials contend. There are, however, a number of key challenges for Canada to face if the precautionary principle is to be incorporated into Canadian regulations.¹⁴²

Canada's current regulatory system is essentially antithetical to the precautionary principle. As discussed above, it is based on an approach to science and regulation that focuses on avoiding regulatory action until the scientific evidence of a problem is irrefutable. Instead, the regulatory system

will have to develop different tools, especially using precautionary science. Such science is rarely practiced in the Canadian food and agriculture system, but the basics of it are reasonably well understood.¹⁴³

Canada needs to develop a goals-based approach to food and agriculture development, like that proposed in this report, as another essential component of the precautionary approach. Such an approach would result from a public discussion about the kind of food and agricultural system Canada wishes to have, with specific targets and resources dedicated to achieving them.

New methods are needed to implement precaution-based decisions. Pollution prevention and phase-outs, for example, are two approaches to the implementation of the precautionary principle. Appropriate variants of these approaches would need to be developed for other food safety applications.

The federal government recently released a draft discussion paper on precaution.¹⁴⁴ It has been widely criticized by environmental non-government organizations (NGOs) for displaying a limited understanding of the principle and how it can apply,¹⁴⁵ and does not reflect the type of application of the principle called for here.

¹⁴¹ Levidow, L. et al. 1997. *Environmental risk disharmonies of European biotechnology regulation*. Centre for Technology Strategy, Open University, Milton Keynes, UK.

¹⁴² According to Tickner, making the precautionary principle operational requires a goal-setting approach to development, new tools for decision-making, and different methods for carrying out prevention-based decisions. (Tickner, J. 1997. Precautionary principle. *The Networker: The Newsletter of the Science and Environmental Health Network*. 2(4), May.)

¹⁴³ MacRae, R.J. et al. 1989. Agricultural science

and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219; Barrett, K. and Raffensperger, C. 1999. Precautionary science. In: C. Raffensperger and J. Tickner (eds.). *Protecting Public Health and the Environment: implementing the precautionary principle*. Island Press, Washington. pp. 106–122.

¹⁴⁴ Government of Canada. 2001. *A Canadian Perspective on the Precautionary Approach/ Principle: Discussion Document*. September 2001.

¹⁴⁵ See Pollution Probe's report on the

7.3 Carry Out Comparative Technology Assessments

As part of the implementation of the precautionary principle, regulators must carry out comparative technology assessments to identify which approaches to solving problems in the food system are most likely to produce optimal societal benefits with minimal risks.

Once a food policy has been established, technology assessment becomes feasible, since the policy sets out the broad evaluative criteria for the assessment. Assessors examine proposed technologies in light of their capacity to fulfill the established food policy.

Currently, the Canadian regulatory system has no capability for doing this. Such assessments have, however, been carried out by independent researchers¹⁴⁶ and by agencies within other governments,¹⁴⁷ so methodologies have been established. In Europe, some of this thinking has been incorporated into decision-making, affecting decisions about production aids in animal production, environmental stewardship, pesticide registration, and genetic engineering. There is growing recognition of the need to broaden the assessment process at an international level. For example, the *BioSafety Protocol* permits countries to use socio-economic factors as part of their process for

reviewing trade in living genetically-modified organisms (GMOs), including “socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.”¹⁴⁸

Establishing the capacity to perform such assessments is multifaceted and multidisciplinary, and (given current regulatory and scientific culture) requires a profound shift in the way governments and scientists think about science, policy-making and social values. Ideally, it begins at the research phase, before technologies are submitted to regulators for approval. Some have proposed that researchers need to consider the relevance of their projects to food policy goals, and that research funding agencies should require that such assessments be carried out in parallel with the funded project.¹⁴⁹ If this happens, reviews at this stage would winnow out technologies that are not appropriate and reduce the review burden at the regulatory stage. At a regulatory level, multidisciplinary teams of assessors are required, since the assessment process is about the interplay between science (particularly ecology and health), economics, policy and social values. As environmental and human

precautionary principle for a full discussion (Pollution Probe. 2001. *Applying the Precautionary Principle to Standard Setting for Toxic Substances in Canada*. Pollution Probe, Toronto. <http://www.pollutionprobe.org/Publications/Policy.htm>) and a critique by the Canadian Environmental Law Association, <http://www.cela.org>.

¹⁴⁶ A pertinent GE example is the comparison of rBGH and rotational pasture management as different approaches to improving milk yields. See Liebhardt, W.C. (ed.) 1993. *The Dairy Debate: consequences of Bovine Growth Hormone and rotational grazing technologies*. University of California SAREP, Davis, CA.

¹⁴⁷ For example, from 1971–1995, the US Congress Office of Technology Assessment carried out these kinds of assessments in a full range of areas including agriculture and food.

¹⁴⁸ *Cartegena Protocol on Biosafety to the Convention on Biological Diversity*. 2000. Secretariat to the Convention on Biological Diversity, Montreal.

¹⁴⁹ For an overview, see MacRae, R.J. et al. 1989. Agricultural science and sustainable agriculture: a review of the main scientific barriers to sustainable food production and potential solutions. *Biological Agriculture and Horticulture* 6: 173–219.

health safety assessments are so expensive, it is sensible to undertake a technology assessment first. If the technology passes this screening process, a full safety assessment proceeds.¹⁵⁰

Conceivably, this approach could be less costly to governments. For example, if the registration of a new pesticide costs the public sector \$216,000,¹⁵¹ then assessments at the research and technology assessment stage should reduce the number of products put forward for final approval. The savings might be adequate to cover the costs of technology assessment units.

7.4 Encourage the Adoption of Ecological Farming Systems that do not Generate so Many Food Safety Hazards

A preventive approach means examining food production methods and encouraging farming systems that do not generate so many food safety hazards. Farm organizations and governments now understand this (in a limited way), since they have devoted significant resources over the past few years to the Canadian On-farm Food Safety initiative, coordinated by the Canadian Federation of Agriculture. However, this approach (essentially bringing HACCP back to the farm) fails to tackle the question of how the design of farming systems generates hazards. There is now a lot of information on how certain farming systems reduce hazards, one of the most significant being farming systems designed around agro-ecological theory.

These agro-ecological farming systems involve design and management procedures that work with natural processes to conserve all resources, as well as minimizing waste and environmental damage, while maintaining or improving farm profitability. They are designed to take maximum advantage of existing soil nutrient and water cycles, energy flows, beneficial soil organisms, and natural pest controls. By capitalizing on existing cycles and flows, environmental damage can be avoided or minimized. Such systems also aim to produce food that is nutritious, and uncontaminated with products that might harm human health. In practice, such farming operations have tended to reduce or avoid the use of synthetically compounded fertilizers, pesticides, growth regulators, and livestock feed additives. These synthetic substances are usually rejected on the basis of their dependence on non-renewable resources, potential for environmental disruption, and possible adverse impacts on soil organisms, wildlife, livestock and human health. Farmers rely more on crop rotations, crop residues, composted animal manures, legumes, green manures, off-farm organic wastes, appropriate mechanical cultivation or minimal tillage to optimize soil, biological and natural pest control activity, and thereby maintain soil fertility and crop productivity. In addition, resistant varieties, and biological and cultural controls are used to manage pests, weeds and diseases. Preventative health care strategies, such as dietary changes, increased exercise, and housing changes are employed to maintain animal health.¹⁵²

¹⁵⁰ For more on this, see MacRae, R.J. and the Toronto Food Policy Council. 1999. Not just what, but how: creating agricultural sustainability and food security by changing Canada's agricultural policy-making process. *Agriculture and Human Values* 16: 187–201.

¹⁵¹ This is the figure used by the Pest Management Regulatory Agency (PMRA).

¹⁵² MacRae, R.J. et al., 1990. Farm-scale agronomic and economic conversion to sustainable agriculture. *Advances in Agronomy* 43: 155–198.

There are many schools of farming within the agro-ecological framework,¹⁵³ the most recognizable currently being organic farming. Organic farming and food processing standards¹⁵⁴ do not permit a number of products and practices that generate food safety hazards, including those related to the following:

Synthetically Compounded Pesticides — almost all pesticides believed to have potentially negative health impacts on humans are not permitted in organic production. Consequently, residues of production pesticides are almost always lower in organic foods.¹⁵⁵ However, organic farmers are unable to control atmospheric deposition of airborne pollutants; consequently, organic food is not residue-free.¹⁵⁶

Fertilization — in contrast to conventional farmers, organic farmers are not permitted to use uncomposted manure, except under very specific circumstances. The composting process reduces pathogen levels and the leaching of nutrients.

Animal Rearing Practices — growth hormones are not permitted, and animals must be fed a diet for which their digestive system is adapted. Consequently, the digestive conditions associated with elevated *E. coli* 0157:H7 levels do not normally occur on organic farms.¹⁵⁷ Mycotoxin levels in animal feeds

are no higher than in conventional agriculture, and some European studies have found lower levels in organic milks than conventional milk.¹⁵⁸ Standards do not permit the use of antibiotics, unless the life of the animal is in jeopardy. Most standards then require that the animal be removed from the organic stream, although some permit its return following an extended withdrawal period. As a result, it is not possible for production practices to create antibiotic resistant bacteria.

Synthetic Preservatives and Additives, and Irradiation — the use of synthetic preservatives and additives is severely restricted, largely to materials derived from naturally-occurring substances. Food irradiation is not permitted.

Genetically Engineered Organisms and Products Derived from Them — these are not permitted in organic farming or food processing, except in cases where no organic sources exist, and conventional ones may be inadvertently contaminated.

Because of these rules (and the ecological principles that underlie them), global trade in organic food products is not seen to be either desirable or viable in the long-term. It is tolerated, at present, because of the gap between supply and demand that exists within nations in this

¹⁵³ For a review, see MacRae, R.J. et al., 1990. Farm-scale agronomic and economic conversion to sustainable agriculture. *Advances in Agronomy* 43: 155–198.

¹⁵⁴ See, for example, standards with international relevance developed by the International Federation of Organic Agriculture Movements (IFOAM). <http://www.ifoam.org>.

¹⁵⁵ See studies reviewed in FAO. 2000. *Food safety and quality as affected by organic farming*. Twenty Second FAO Regional Conference for Europe, Porto, Portugal, July 2000.

¹⁵⁶ See, for example, Woese, K. et al. 1997. A comparison of organically and conventionally grown foods — results of a review of the relevant literature. *J. Sci. Food Agric* 74: 281–293.

¹⁵⁷ FAO. 2000. *Food safety and quality as affected by organic farming*. Twenty Second FAO Regional Conference for Europe, Porto, Portugal, July 2000.

¹⁵⁸ FAO. 2000. *Food safety and quality as affected by organic farming*. Twenty Second FAO Regional Conference for Europe, Porto, Portugal, July 2000.

nascent stage of organic farming's development. However, most organic farming proponents and practitioners believe that selling into local markets is the long-term objective.

The Canadian government has yet to invest significantly in organic farming and food distribution. Governments in Europe have, however, and dramatic increases in organic farming adoption

and market share have been the result. Policy and programme proposals have been made to the federal government, outlining how governments can invest in the organic farming sector, and reap the multiple benefits that will flow from such an investment.¹⁵⁹ It remains to be seen whether the new Agricultural Policy Framework will take advantage of this opportunity.

¹⁵⁹ See, for example, World Wildlife Fund Canada. 2000. *Making Pesticide Reduction a Reality in Canada*. Available at: <http://www.wwfcanada.org/satellite/prip/resources/resources.html>.

Appendices

The appendices that follow provide additional information on food safety hazards and some of the technologies that generate them. These are not exhaustive treatments of what are clearly complex subjects, but rather elaborate on some of the issues that have been raised in this report.

Appendix A: Microbial Hazards

Description

Disease from food-borne pathogens is the most serious *acute* problem associated with contaminated food or beverages in North America. More than 200 known diseases are transmitted through food by a variety of parasites, bacteria and viruses.

Many of the food-borne illnesses today were not known twenty years ago. Better scientific testing methods have allowed experts to identify numerous, previously-unknown pathogens that cause sickness and, in some, cases death.

The most commonly recognized food-borne illnesses are those caused by the bacterium *Campylobacter*, *Salmonella*, specific strains of *Escherichia coli* and a group of viruses known as the Norwalk viruses. Seventy-five per cent of all food poisoning deaths are associated with three pathogens: *Salmonella*, *Listeria* and *Toxoplasmosis*.

Food-borne pathogens are transmitted by a variety of food products — meats, fish, poultry, milk, and eggs — but probably the most pervasive form of transmission is through undercooked meats. *Campylobacter jejuni*, *E Coli 0157:H7*, *Toxoplasma gondii*, and *Salmonella* are all transmitted through the consumption of undercooked poultry or ground meat.

Other meats can also transmit these pathogens to humans.

The transmission of other food-borne pathogens is generally via other vectors. *Listeria monocytogenes* is often found in dairy products, vegetables and fish. *Salmonella* can also be transmitted through fruits and vegetables, if they have come from soil contaminated by animal feces. One of the less common, but potentially fatal food-borne illnesses is *Clostridium botulinum*. Canned and especially home canned foods are most likely to contain *C. botulinum*.

There are a number of illnesses associated with the consumption of tainted fish. These include illnesses caused by fish contaminated by bacteria, other microorganisms or marine biotoxins. Marine biotoxins either occur naturally in fish or shellfish, or are absorbed from their environment. Many biotoxins are produced by microscopic marine algae (phytoplankton, including diatoms and dinoflagellates) and can accumulate in fish or shellfish if they ingest these algae. There are several types of illnesses, caused by marine biotoxins that are connected with the consumption of contaminated fish and shellfish. They include paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), and diarrhetic shellfish poisoning (DSP) and ciguatera poisoning.

Known Health Risks

In the United States, the Centers for Disease Control and Prevention (CDC) estimates that there occur over 76 million illnesses and over 5,000 deaths a year relating to food-borne pathogens. Health Canada estimates that every year approximately two million Canadians suffer from illnesses caused by food-borne bacteria and about 30 of them die. Health Canada also estimates that the annual costs related to these illnesses and deaths exceed \$1 billion.¹⁶⁰

Outbreaks of food poisoning are not uncommon, with recent outbreaks in Moncton (New Brunswick) and Nunavut in 2000 caused by hamburger found to contain a lethal strain of *E. coli*.

Early symptoms of most food-borne illnesses are gastrointestinal, including nausea, vomiting and diarrhea. In many cases, these symptoms are mistaken as

manifestations of the common flu virus. Some pathogens can evoke more serious health risks including death. *E. coli O157:H7* is known to cause hemorrhagic colitis and, in 5–10 per cent of cases, hemolytic uremic syndrome (HUS), a severe life-threatening complication. *C. botulinum* can cause, in some cases, paralysis. Seafood toxins are also known to cause paralysis and death.

Cases of food-borne disease are often most serious in the elderly and in very young children. The immature immune systems of children make them more susceptible to food-related illnesses than those of healthy adults. *Listeriosis*, *E. coli O157:H7*, *Toxoplasma* and *Salmonella* can have serious effects on children. HUS is the most common cause of kidney failure in childhood. *E. coli O157: H7* is responsible for over 90 per cent of the cases of HUS that develop in North America.¹⁶¹

¹⁶⁰ Canadian Partnership for Consumer Food Safety Education “Bacterial Food-borne Illness in Canada” <http://www.canfightbac.org/english/mcentre/mkit/foodborne.shtml>

¹⁶¹ <http://www.about-ecoli.com/>

Appendix B: Pesticides

Description

Synthetic pesticides, broadly termed, have been widely used for pest and weed control in agriculture in Canada since the 1940s. They have been used primarily to increase crop yields by preventing losses caused by pest infestations. Pesticides by their nature are designed to be toxic against target organisms and they are used to kill weeds, insects, fungi, bacteria and other organisms. Most pesticides kill both target and non-target species. In addition, pesticides are often used to protect fresh produce from spoiling. The amounts and varieties of pesticides we use today are far greater than at any other time in history. In Canada, there are over 7,000 individual pest control products available on the market, generating over \$1.4 billion in sales.¹⁶²

There are many classes of pesticides in use in Canada, including organochlorines, organophosphates, carbamates, synthetic pyrethroids, aldehydes, and amides (see Table 2). Organophosphates and carbamates are the most widely used agricultural pesticides, first used in the 1940s, and unlike organochlorines have a short half-life and are not persistent in the environment.

Due to the heavy use of pesticides in agriculture, traces of pesticide residues are often found on foods we eat. These residues may be present directly on the raw foods, such as fruit and vegetables, or they may be ingested second-hand through animal products. Animals that are fed pesticide-treated food can build up toxics in their fatty tissue. These toxic compounds can be passed on to humans who consume them.

Of the 44,379 samples of food analyzed between 1994 and 1998 by the Canadian Food Inspection Agency, almost 25 per cent of the total samples were found to have detectable levels of residue and close to five per cent did not meet current safety guidelines.¹⁶³

Imported produce was found to have pesticide residues of both permitted and banned pesticides. Specific residue findings show occurrences of banned categories of pesticides including organochlorines, such as DDT and its metabolites, aldrin, endrin, heptachlor, and lindane.^{164, 165}

¹⁶² Crop Protection Institute. 1998. *Sales Survey Pest Control Product in Canada, Report and Discussion*.

¹⁶³ Canadian Food Inspection Agency. 1999. *Levels and Incidences of Pesticide Residues in Selected Agricultural Food Commodities in Canada*.

¹⁶⁴ *Pesticides: Making the Right Choice*. Report of the Standing Committee on Environment and Sustainable Development. May 2000.

¹⁶⁵ Also see the FoodWatch web site (<http://www.foodwatch.ca>) for additional information on residues.

Table 2: Key Categories of Pesticides in Canada

Class of Chemical Pesticides	First Used	Examples	Status	Effects
Organo-chlorines	1942	aldrin, dieldrin lindane, DDT	lindane, methoxychlor & PCP registered in Canada	persistent, bioaccumulative, affect ability to reproduce
Organophos-phates	Early 1940s	schradan, parathion malathion	schradan discontin- ued in 1964; many OP under review and likely to be restricted	non-persistent, systemic, not very selective, toxic to humans
Carbamates	1930 but used in 1950s	carbaryl, aldicarb	All registered except aldicarb; many under review	non-persistent, cholinesterase- inhibiting, not very selective, toxic to birds and fish
Phenoxy	1946	2,4-D 2,4,5-T	2,4,5-T banned	2,4-D potential to cause cancer in lab animals; 2,4,5-T a source of dioxin
Pyrethroids	1980	fenpropanthrin deltamethrin; cypermethrin	fenpropanthrin not registered	target-specific, more selective than organophosphates or carbamates, generally not acutely toxic to birds or mammals, toxic to fish

Table 3: Percentage of Fruits/Vegetables with Detectable Pesticide Residue Levels (1994–1998)

Total number of Positive Samples	Fresh	Processed
Domestic	1710 (24.8%)	33 (8.7%)
Imported	8767 (25.3%)	172 (6.8%)

Health Risks

Pesticides by their nature are highly toxic, and are known to cause a variety of health disorders including cancer, hormonal imbalances, malformations of the reproductive organs, immune suppression, birth defects, neurotoxicity, learning disabilities and attention deficit disorders, infertility, impaired childhood development, and toxicity to the liver, kidney, skin and brain. Even minute doses of many organochlorines can be extremely toxic.

The health effects of pesticides are known to be synergistic. A combination of only two different organochlorines mixed together in minute doses has been found to be 1,000-times more potent in affecting human estrogen receptors as either chemical alone. For example, dieldrin, endosulfan and toxaphene, by themselves, stimulate only mild growth of breast cancer cells in culture, but show greater than additive effects when given together.¹⁶⁶ Although the amount of one pesticide residue may not be greater than the maximum allowable level, several pesticides from the same class acting at the same site in the body can have a cumulative toxic effect.

Due to their small size and weight and their physiological immaturity, children are susceptible to pesticide exposure. In infants, there is decreased elimination of pesticides through the intestinal tract due to reduced bile flow, caused by inefficient fat digestion. This can result in the

bioaccumulation of toxic compounds in a child, and may cause both acute and chronic disorders. The result is that for some pesticide compounds, the lethal dose in immature animals is just one per cent of that in adult animals.¹⁶⁷

Children may be exposed to a high concentration of pesticides through the consumption of breast milk, or through the consumption of foods with high pesticide residues. In an analysis by the Consumers Union of the US done in 1998, nine high-intake foods were deemed most likely to contribute to dietary insecticide exposure in children. The nine foods are apples, pears, peaches, grapes, oranges, peas, green beans, potatoes and tomatoes. Each of these fruits and vegetables has been found to have high residues of organophosphates (OPs) and carbamates. The highest risk OP compounds are methyl parathion, dimethoate, chlorpyrifos, pirimiphos methyl and azinphos methyl. These account for more than 90 per cent of the risk from OP insecticides.¹⁶⁸

The National Campaign for Pesticide Reform in the US noted that by the age of five, millions of children have ingested 35 per cent of their lifetime dose of some carcinogenic pesticides.¹⁶⁹ In Canada, in a study by the Ontario College of Family Physicians, co-author of the study Dr. Loren Vanderlinden said, "We believe that the cumulative effects of being exposed to so many different pesticides over a lifetime represents an undeniable risk to all Canadian children."¹⁷⁰

¹⁶⁶ Sat Dharam Kaur, N.D. 2000. *A Call to Women: The Healthy Breast Program and Workbook*. Quarry Press.

¹⁶⁷ Spyker, J.M. and D.L. Avery. 1977. Neurobehavioral Effects of Prenatal exposure in the Organophosphate Diazinon in Mice. *Journal of Toxicology and Environmental Health*. pp.

989–1002.

¹⁶⁸ Ibid. p.5.

¹⁶⁹ *Worst First: High-Risk Insecticide Uses, Children's Foods, and Safer Alternatives*. March 1999.

¹⁷⁰ Study shows pesticide exposure hurting Canadian children. Andrew Duffy, *Southam News*.

There is evidence that pesticide exposures cause a range of chronic health effects in children, including immune disorders, neurotoxicity, reproductive impacts, disruptions in endocrine function, behavior disorders and cancer. Pesticide ingestion has been linked with lower intelligence and less-developed motor skills in children, as well as endocrine disruption. Animal studies have shown that the young tend to exhibit greater sensitivities to pesticides and that

pesticide effects may manifest themselves later in life. However, it is difficult for scientists to identify the direct causal link between the long-term low-dose accumulation of a variety of pesticides in the human body and the subsequent manifestation of disease. That being said, there is significant evidence from scientific work to date in animals that shows there is a great likelihood that the health of children is being compromised by pesticide exposure.

Appendix C: Growth Hormones

Description

Many countries, including Canada, use hormone implants as growth promoters to increase the production of meat in cattle. Several naturally-occurring hormones (including testosterone, progesterone and estradiol-17 β) and synthetic hormones (trenbolone acetate, zeranol and melengestrol acetate) have been used to increase muscle tissue growth (that is, meat production) by supplementing natural hormone levels. This is a practice that has been widespread since the late 1950s.

The use of anabolic implants in beef cattle production has become standard practice across North America due to the implants' effects on improving growth performance and lean yield among cattle.

There are currently seven beef hormones, including implants, approved in for use in Canada:

- **Synovex H** (a combination of 20 mg estradiol benzoate and 200 mg testosterone propionate) — approved 1958.
- **Synovex S** (a combination of 200 mg progesterone and 20 mg estradiol benzoate and tartrazine) — approved 1958.
- **Ralgo** (36 mg zeranol) — approved 1973.
- **MGA 100 Premix** (220 mg of melengestrol acetate per kilogram of Premix) — approved 1986.
- **Revalor-S**, a brand name beef hormone implant for steers (a mixture of 24 mg of estradiol and

120 mg of trenbolone acetate) — approved 1994.

- **Revalor-H**, a brand name beef hormone implant for heifers (a mixture of 14 mg estradiol and 140 mg trenbolone acetate) — approved 1997.
- **Synovex +**, a brand name beef hormone implant for steers and heifers (a mixture of 28 mg estradiol benzoate and 200 mg trenbolone acetate) — approved 1995.

Health Risks

Growth hormones may be linked to cancer and other abnormalities in humans and animals. European scientists have concluded that the one primary ingredient in growth hormones, estradiol-17 beta, is carcinogenic.¹⁷¹ These findings have yet to be widely confirmed by research, but are the basis of an emerging scientific discussion within the international research community.

The health implications associated with beef growth-promoting hormones are not well defined. These compounds have been deemed safe in Canada based on our risk assessment processes, as well as assessments by a peer-reviewed panel of international scientists. Yet concerns over possible links between some growth-promoting hormones and health effects in animals and humans have persisted in the European scientific community and within Health Canada. The EU's ban of the use of hormones as beef growth promoters in 1988 and its refusal to withdraw the ban on imported meat

¹⁷¹ *Globe & Mail*, July 19, 1999. p. 20.

containing hormones are grounds for concern.

In looking at the evidence from Europe, a report of the EU's Scientific Committee on Veterinary measures relating to Public Health (SCVPH)¹⁷² identified the following health risks: "In the case of 17 β -oestradiol... a substantial body of recent evidence [suggests] that it has to be considered as a complete carcinogen, as it exerts both tumor initiating and tumor promoting effects." However, no quantitative estimate of risks was available for the other hormones (for example, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate). For all other hormones, the committee claimed, "endocrine, developmental, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged" (with prepubescent children being the group of greatest concern). No threshold levels could be defined for any of the six substances.¹⁷³

At Health Canada, a major debate took place regarding Revalor-H when several key scientists working for the Bureau of Veterinary Drugs (BVD) publicly expressed concern about the safety of the compound. The hormones identified potentially have their greatest impact on children. Revalor-H, which contains the compound 17 β -oestradiol, has been claimed to induce early puberty and abnormal growth of mammary tissue in young

female calves, while male calves receiving the hormone develop "tremendously enlarged" prostate glands.¹⁷⁴

One of the more startling pieces of scientific work was a study of 17,077 US girls by Dr. Marcia Herman-Giddens, et al., which found the average age for onset of puberty is now nine, two years earlier than in the 1960s.¹⁷⁵ Current medical texts say puberty begins at between 11 and 12 years, on average, so a two-year drop in the age of onset in one generation is an alarming phenomenon. Some groups have claimed that better diets have led to the earlier onset of puberty, but a biological shift of this magnitude over such a short period of time would be surprising if based on diet alone. Increased exposure to hormone disrupters either through food or other mediums could play a role.

An independent panel in the United Kingdom, the Sub-Group of the Veterinary Products Committee, has challenged these claims.¹⁷⁶ This group voiced concern over the scientific reasoning in several key areas, including the link between hormonally-active residues in meat, cancers, and human development and reproduction.

The above opinions also contrast with the case presented by the users of beef growth-promoting hormones; scientific evaluators, review panels and researchers have all officially concluded that the use

¹⁷² Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health: *Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products*. Section 5.

¹⁷³ Food Ethics Council. *Drug Use in Farm Animals*. 1999. p.13.

¹⁷⁴ Proceedings of the Senate Standing Committee on Agriculture and Forestry. Issue 35, Evidence — Morning Sitting. May 3, 1999.

¹⁷⁵ Herman-Giddens, M.E., E.J. Slora, R.C. Wasserman, C.J. Bourdony, M.V. Bhapkar, G.G. Koch and C.M. Hasemeir. 1997. Secondary sexual characteristics and menses in young girls seen in office practice: a study from the pediatric research in office settings network. *Pediatrics* 99(4): 505–512.

¹⁷⁶ United Kingdom, Veterinary Medicines Directorate. Final Report of the Sub-Group of the Veterinary Products Committee. October 19, 1999.

of beef hormones for growth promotion purposes, a practice taking place in Canada since the 1960s, does not pose health risks to humans. Numerous countries, including Canada and the United States, have approved various hormones and combinations of hormones for use in beef production after rigorous analyses of scientific data.

Much of the ongoing debate around hormones is based on whether scientific findings have any bearing on human health in the context of existing exposure levels stemming from the consumption of meat and meat products. This issue may need to be addressed with additional research.

Appendix D: Food Irradiation

Description

Food irradiation was a process discovered by scientists in the 1930s and 40s, and pushed onto the market by commercial interests. In Canada, the Crown corporation Eldorado Mining and Refining, intent on finding markets for radium and the radioisotope by-products of uranium processing, was the key driver of the technology's development. The first commercial food irradiator was built in Canada in 1963. None of the irradiators operating in this country are intended strictly for food processing, relying for the most part on medical sterilization for their revenue. Irradiation involves exposing food to gamma rays emitted by Cobalt-60 or Cesium-137 to kill bacteria present in food products. Canada also produces much of the fuel for irradiators: Cobalt-60 is created by placing mined Cobalt-59 in nuclear reactors.¹⁷⁷ Given the risks related to exposure to food pathogens as described in Appendix A, irradiation has been marketed as one way to enhance the safety and quality of the food supply. Food manufacturers have used it since the 1980s to kill pathogens in many foods, thus helping extend a food's shelf life.

Irradiation is approved in Canada for use in potatoes, onions, wheat, wheat flour and spices. Currently, only a small percentage of the spices consumed in Canada are being irradiated.¹⁷⁸ There has been some support for making irradiated

meat widely available.¹⁷⁹ Worldwide, at least 50 countries permit the irradiation of food.¹⁸⁰ To varying degrees, there are about 20 countries that practice food irradiation.¹⁸¹

Health Risks

The safety of food irradiation has been debated for years. The Food Safety Consortium in the US claims irradiation is safe and there have been a number of endorsements from international organizations, such as the American Medical Association and the World Health Organization. In Canada, both Agriculture Canada and Consumer and Corporate Affairs Canada endorse food irradiation.¹⁸² The Joint Study Group on High Dose Irradiation also concluded, "food irradiated to any dose appropriate to achieve the technological objective was both safe and nutritionally adequate."¹⁸³

Those questioning the safety of irradiated foods include The Canadian Medical Association, the Consumer Health Organization of Canada, some food scientists, the Organic Growers Association and a variety of activist groups.

The safety questions surrounding irradiated foods include potential biochemical and physiological problems, such as polyploidy (that is, a cell having more than two sets of homologous chromosomes) or other toxic responses.

¹⁷⁷ Strauss, S. 1998. How we built a germ zapper we won't use. *Globe & Mail*. January 8.

¹⁷⁸ Holmes, R. 1994. *Additive Alert*. McClelland & Stewart. p.186.

¹⁷⁹ Editorial, *Globe & Mail*, July 3, 2000. p.A12.

¹⁸⁰ Loaharanu, P. 1994. Status and prospects of

Food irradiation. *Food Technology*. 48(5): 124–130.

¹⁸¹ Holmes, R. 1994. *Additive Alert*. McClelland & Stewart, p.188.

¹⁸² *Globe & Mail*, July 3, 2000, p.12.

¹⁸³ Kneen, B. Letter to Codex Contact Point for Canada. December 30, 1999.

In addition, there are concerns about the effect of irradiation on the nutritional degradation of foods for which irradiation is permitted.

One key study was issued by the Ministry of Health, of the Government of India, in the mid-1970s. The institute found that:

- rats and mice fed diets containing freshly irradiated wheat showed increased levels of polyploid cells;
- normal monkeys and undernourished children fed diets containing freshly irradiated wheat showed increased levels of polyploid cells in white blood cells; and,
- mice fed irradiated wheat showed increased numbers of prenatal deaths.¹⁸⁴

The impact of polyploid cells is still not clear, although they are often seen in association with rapidly regenerating tissues and with certain malignancies. The Indian study has been debated intensely. Health Canada dismissed the study, indicating that polyploidy may have been linked to the children's

malnourishment before the study. This does, however, bring into question the impact of irradiated foods on a high number of malnourished children worldwide.

The FDA's adoption of food irradiation in the US was based upon a small number of studies (five) from the more than 400 available. Two of the studies had problems with statistical significance and unexplained deaths.¹⁸⁵

Other research shows fewer causes for concern. Thayer noted that more than 40 years of animal studies have shown no toxic effects from eating irradiated foods.¹⁸⁶ Free radicals formed when food is exposed to irradiation, potentially thought to be a health concern, have been shown by some researchers to be the same as those formed by other forms of food preparation, like steaming or roasting.¹⁸⁷

There are still outstanding questions regarding the impact of irradiation on foods treated with pesticides. Little research has been done to show what, if any, chemicals are released by the treatment of pesticide-laden fruits and vegetables with irradiation.

¹⁸⁴ Srikantia, S.G. Testimony from US Congressional Hearings into Food Irradiation. June 1987.

¹⁸⁵ Louria, D. Testimony from US Congressional Hearings into Food Irradiation. June 1987.

¹⁸⁶ Thayer, D.W. 1994. Wholesomeness of irradiated foods. *Food Technology*. 48(5): 132–135

¹⁸⁷ Diehl, J.F. 1995. *Safety of Irradiated Foods*. Marcel Dekker Inc. New York, NY.

Appendix E: Food Additives

Description

Humans have used natural food additives for centuries. Salt, sugar and vinegar were among the first additives used to preserve foods. Herbs and spices were used to improve the flavor of foods. But, over the last 30 or so years, with the development of the processed food industry, there has been an explosion in the use of additives. In Canada, there are between 350 and 450 food additives approved for use. This does not include flavoring agents that are considered by Health Canada to be food ingredients.¹⁸⁸

Canadians are accustomed to an abundant, inexpensive food supply. We can buy most foods and vegetables year-round, and an array of processed foods is also available. We have come to expect that food will have consistent quality

over time. Much of this is possible because of food additives. In its broadest sense, a food additive is any substance added to food. More specifically, food additives can be defined as a “substance which results in it or its by-products becoming a part of or affecting characteristics of a food.”¹⁸⁹

Originally, additives were developed to extend the shelf life of processed foods. Such additives are added to food during processing to prevent spoilage, preserve flavor and help prevent food-borne illness from foods left on the shelf or in the refrigerator for long periods of time. Additives are also used in a variety of other ways, such as to adjust the color or appearance, improve nutrition, and aid in processing (e.g., thickeners and emulsifiers).

Class of additive	Property of food influenced
Preservatives	Shelf life
Colorings	Appearance
Flavorings and Flavor	Enhances Flavor
Antioxidants	Shelf life
Artificial sweetening substances	Flavor, energy value
Vitamins and minerals	Nutritive value

¹⁸⁸ Holmes, R. 1994. *Additive Alert*. McClelland & Stewart.

¹⁸⁹ St. Onge, L. Why Use Additives, Food Processing Development Centre.

Modifying agents	Property of food influenced
Vegetable gums	Texture, appearance
Minerals salts	Texture, appearance
Food acids	Shelf life, flavor, texture
Emulsifiers	Texture, appearance
Humectants	Texture, shelf life
Thickeners	Texture, appearance

Other miscellaneous additive classes are acids, acidity regulators, anti-foaming agents, anti-caking agents, bulking agents, carriers and carrier solvents, emulsifying salts, firming agents, flavor enhancers, foaming agents, gelling agents, glazing agents, some modified starches, packaging gases, propellants, raising agents, sequestrant agents and stabilizers.

Health Risks

Considerable controversy has been associated with the potential threats and possible benefits of food additives. The majority of food additives are considered to be non-hazardous, although there are on-going debates as to the safety of certain food additives. Some are known to be carcinogenic or toxic, and particular disorders such as hyperactivity in children, allergies, asthma and migraines are often associated with adverse reactions to food additives. A number of food additives have been linked to cancer in laboratory animals. Some of these include: the sweetener Aspartame; the preservatives BHA, BHT, nitrates and nitrites; the flavor enhancer MSG; and texture modifying agents, such as carrageenan.

Sulfites are one additive group that pose many unresolved questions. Sulfites are often added to baked goods, condiments and snack foods, and are used as preservatives and as anti-oxidants to prevent discoloration of foods. A small segment of the population, however, may exhibit allergic reactions (developing hives, nausea, diarrhea, shortness of breath or even fatal shock) after consuming sulfites.¹⁹⁰ In Canada, labeling is required to try and protect those in the population who may have an adverse reaction to sulfites (although there has been little public education as to the potential danger of this additive).

Given the scientific concern about the health impacts of certain additives, there are questions as to the cumulative and synergistic effects of these additives on human health. So far, it is not known whether additives have either a synergistic or cumulative effect.

Attention-deficit hyperactivity disorder (ADHD) is a neurobehavioral disorder in children that is characterized by

¹⁹⁰ Holmes, R. 1994. *Additive Alert*. McClelland & Stewart.

inattentiveness, impulsiveness, and hyperactivity. There are conflicting views on whether food additives contribute to hyperactivity in children. A Consensus Development Panel of the National Institutes of Health in the US concluded in 1982 that there was no scientific evidence to support the claim that additives or colorings cause hyperactivity. However, a number of studies suggest otherwise.¹⁹¹ The International Food Information Council said that for some children with ADHD and a confirmed food allergy, dietary modification has produced some improvement in behavior.¹⁹²

In the mid 1970s, Feingold published his hypothesis that the elimination of certain food additives from the diets of hyperactive children can result in improvement of behavioral symptoms.¹⁹³ Feingold's hypotheses have been challenged in a number of subsequent

studies. A 1986 review of studies that evaluated the Feingold diet concluded that there is no evidence for a causal association between food additives and behavioral disturbance in children.¹⁹⁴

The safety of food additives manufactured through the use of microorganisms produced by recombinant DNA techniques is unclear. With food additives, it is necessary to evaluate concomitant issues introduced by use of recombinant DNA techniques, including: the recombinant itself; physiologically active substances produced by the recombinant; product contamination by cultured components; and changes of ordinary constituents in a product. The safety of food additives manufactured through the use of microorganisms produced by recombinant DNA techniques should be better understood.

¹⁹¹ US Food and Drug Administration FDA/IFIC Brochure: January 1992.

¹⁹² Food Additives. <http://ifinfo.health.org/brochure/food-add.htm>.

¹⁹³ Feingold B.F. 1975. *Why Your Child is*

Hyperactive. New York. Random House.

¹⁹⁴ Wender, E.H. 1986. The food additive free diet in the treatment of behaviour disorder: a review. *J Dev Behav Pediatrics*. 7: 35–42.

Appendix F: Functional Foods

Description

“Let food be your medicine” is a time-honored maxim, with good data to support it. However, there is a significant difference between this approach and the use of functional foods, which might be described as “turning food into medicine.” The Bureau of Nutritional Sciences, of the Food Directorate of Health Canada, defines functional foods as follows:

“A *functional food* is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.”¹⁹⁵

The drive to develop functional foods is a market-driven response to consumer interest in nutritional health and the opportunities created by the failure of our food policies to maintain a healthy population. The market for functional foods is growing rapidly worldwide, and is perceived to be potentially worth hundreds of billions of dollars; food companies believe functional foods to be a way to improve health and reduce health care costs.¹⁹⁶

Functional food products for which health benefits are claimed are emerging in many product categories, including cereals, beverages, chocolate bars, spreads

and yogurts. These products include nutrients from both animal and vegetable sources, such as amino acids, fats, dietary fibers, phytoestrogens, plant pigments, animal pigments, antioxidants, sulphur compounds, vitamins and minerals. Most functional foods on the market are processed foods, where the extra function has been added during processing.

The functional foods of the future could be raw foods modified by biotechnology. Work is on-going to develop rice with new traits (such as Vitamin A enhancement) or tomatoes that contain cancer-fighting substances. Products in development currently include nutritionally-improved canola, soy and wheat from Monsanto. Aventis has a series of products in its development pipeline, including products with modified oil contents, higher lysine levels and modified starches.¹⁹⁷

Health Risks

The risks of functional foods are not well understood. In Canada, it is proposed that functional foods would have to undergo a basic evaluation to ensure the products would not have adverse nutritional or toxicological effects.

In addition, any health claims applied to foods may change the consumption patterns of those foods. In foods containing bioactive substances, this could introduce new and unforeseen exposure issues that would need to be assessed.¹⁹⁸

¹⁹⁵ http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/ffn/nutra_pol_e.html.

¹⁹⁶ Culhane, C. 1995. *Nutraceuticals/Functional Foods: An Exploratory Survey on Canada's Potential*. Summary Report to Agriculture and Agri-Food Canada. International Food Focus

Limited. Toronto, Ontario. June. <http://www.agr.ca/food/markets/nutraceutical/nutra/enutra.html>.

¹⁹⁷ Corporate Watch. 2000. *Functional Foods: Good for Monsanto's Health*.

¹⁹⁸ Standards of Evidence for Evaluating Foods

Concerns about the health effects of functional foods are being weighed against the commercial interest in the marketing of these foods. There is

limited understanding of either the qualitative and quantitative benefits and risks of functional foods.

with Health Claims Synopsis of the Consultation Document. http://www.hc-sc.gc.ca/food_aliment/english/subjects/health_claims/soe_synopsis_consultation.html. 2000.