Health Canada Santé Canada

Your health and safety... our priority. Votre santé et votre sécurité... notre priorité.

2007

Health Products and Food Branch

Towards a Regulatory Modernization Strategy for Food and Nutrition

Health Canada Discussion Document

Canada

TABLE OF CONTENTS

INTRODUCTION

Blueprint For Renewal and Food Regulatory Modernization

In October 2006, Health Canada's Health Products and Food Branch (HPFB) released its *Blueprint for Renewal*[1] plan, a major initiative that presents a vision and objectives aimed at modernizing Canada's regulatory system for health products and food, as well as proposed actions for moving forward.

From October to December 2006, HPFB consulted stakeholders and the general public on the Blueprint plan. This included a series of discussion sessions across Canada, as well as an electronic consultation. As a result of these consultations a revised *Blueprint for Renewal II* plan has been developed and was published in April 2007.

Few governmental tasks are as central to the everyday lives of Canadians as the responsibility to ensure that the food Canadians buy and eat is safe and nutritious, and that Canadians can rely on the truthfulness and accuracy of any claims or advertising made about food sold in Canada. It is also critically important that Health Canada's regulatory system for food and nutrition be able to respond to new challenges – irrespective of their origin – to the effectiveness of regulatory standards, and the ability of such standards to be active and positive contributors to improved health for all Canadians.

Blueprint for Renewal recognizes the important challenges facing Canadians and the Canadian food production chain. Health Canada continues to work with industry, other government departments and concerned Canadians to maintain the safety of Canada's food supply and to help Canadians make healthy food and diet choices. To this end, *a Regulatory Modernization Strategy for Food and Nutrition* (the Strategy) is a key feature of the *HPFB Blueprint for Renewal* and is intended to expand on *Objective # 4* of the *Blueprint for Renewal II*:

> *"Health Canada will design and implement a modern, efficient, and responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace"*

Purpose

The purpose of this document is to provide a basis for a discussion between Health Canada, regulatees, and Canadians about the direction of Health Canada's efforts to modernize its food regulatory system. This document is intended to lead to the completion of a *Regulatory Modernization Strategy for Food and Nutrition* (the Strategy), which will provide strategic

[1] Health Products and Food Branch (HPFB) *Blueprint for Renewal II*:
http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan_ll_e.pdf
HPFB Blueprint for Renewal Webpage:
http://www.healthcanada.gc.ca/hpfb-blueprint

direction for Health Canada planning and program activity, and will be consistent with the principles, priorities, and relevant objectives of the *Blueprint for Renewal*.

Scope

The Strategy will focus on regulatory improvements in those areas of food safety and nutritional quality regulation which are exclusively within Health Canada's jurisdiction. Other related (multi-jurisdictional) issues are alluded to where necessary, but are outside of the scope of this HC strategy.

WHAT IS "FOOD REGULATION"? WHAT IS HEALTH CANADA'S ROLE?

"Food regulation" in Canada can be seen as referring to three distinct elements:

1. A system of standards a) in legislation; b) in regulation; or c) outlined in governmental positions which assign responsibility for, and establish acceptable limits for, and/or influence, the safety and quality of food products and food production inputs as these relate to food safety and quality (including plants, animals, fertilizers, pesticides, veterinary drugs);
2. The establishment of food-related consumer protection standards which identify legal / regulatory requirements for the accuracy of food-related advertising, labelling, and claims; and
3. The system of enforcement for food standards in legislation and regulation and the mechanisms of government which assure compliance with those standards.

In Canada, legislative oversight and regulatory decision-making authority for "food" is a shared responsibility. In general terms this responsibility is divided in three significant ways :

1. Federal responsibilities;
2. Provincial and Territorial (P/T) responsibilities; and
3. Areas of concurrent authority.

Food regulatory responsibilities are further sub-divided into:

(A) Regulation of health and safety for foods[2] under criminal law (e.g. *Food and Drugs Act*[3] and regulations);
(B) Regulation of non-health and safety food quality under trade and commerce law (e.g. *Meat Inspection Act* and regulations, *Health of Animals Act* and regulations, *Seeds Act* etc.); and

[2] Also see *Annex*

[3] *Food and Drugs Act*, under the Federal Minister of Health, is highlighted specifically insofar as it, and activities surrounding them, constitute the principal focus of the Strategy; other examples of legislation which do or may relate to Health Canada's responsibilities for "food regulation" could include the *Department of Health Act*, *Pest Control Products Act (PCPA)*, the *Canadian Environmental Protection Act (CEPA)*, and others – though this legislation is not discussed in this document.

(C) Regulation of consumer protection related to food under consumer protection statutes (e.g. *Consumer Packaging and Labelling Act* (portions), *Food and Drugs Act* (portions), etc.).

The Canadian food safety "system" uses federal legislative requirements and regulatory standards for food safety and nutritional quality, as well as for the safety of certain agricultural inputs, as a baseline beyond which P/T governments may make their own requirements.

It should be noted that any food product that is traded across P/T borders must comply with Federal trade and commerce standards for food and agriculture in addition to basic health and safety requirements. These considerations are controlled through a system of federal registration; enforcement of federal trade and commerce requirements associated with being a "federally-registered" establishment fall within the jurisdiction of the Canadian Food Inspection Agency (CFIA). In the context of food products (and the establishments which produce them) which are produced and sold within a single province or territory, all health and safety provisions of the *Food and Drugs Act* apply (enforced by the CFIA), however federal trade and commerce rules do not apply to these establishments or the products they produce.

Health Canada is responsible for:

- ❏ Standards development for food safety and nutrition issues – and associated policies, guidelines and regulatory processes for those issues within HC's exclusive jurisdiction;
- ❏ "Real-time" risk assessment and/or risk management for threats to human health through food – in support of Canadian Food Inspection Agency (CFIA)[4] enforcement and compliance actions, in support of the Government of Canada (GoC), and/or in support of P/T governments;
- ❏ Scientific evaluation of foods, food processes / components, and other food / agricultural inputs which are submitted for mandated pre-market regulatory approval or notification;
- ❏ Promotion of nutrition as it relates to diet, and promotion of food safety practices;
- ❏ Risk communication to Canadians and to regulatees regarding known and discovered risks to human health through food;
- ❏ Reporting to the Minister of Health, under the *CFIA Act*, on the effectiveness of CFIA food safety programs; and
- ❏ Applied scientific research, surveillance, and monitoring in support of all Health Canada's legislative/regulatory food safety and nutrition responsibilities.

[4] The Canadian Food Inspection Agency (CFIA) is responsible for the enforcement and compliance activities of the Government of Canada (GoC) [under criminal law, trade and commerce law, and consumer protection statute] in the areas of food safety, animal health, plant protection, and non-health and safety food quality issues.

WHY MODERNIZE? IDENTIFYING DRIVERS AND OPPORTUNITIES FOR IMPROVEMENT

Since 1953, the federal government's role and responsibilities for health products and food safety have been primarily defined through the *Food and Drugs Act*. The regulatory approaches embodied in the Act and its regulations were designed to meet the challenges of the day. The Act was largely intended to be a consumer protection statute.

This has had longstanding implications for the role of the regulator. This role was primarily concerned with providing citizens and regulatees with some level of "fair play" within the market for the manufacturing and marketing of food and drugs. However, many things have changed since the 1950s, including the view of citizens on the role of the government in regulation, particularly with respect to product safety, as well as the government's understanding of the value that the regulatory authority provides in advancing important public policy goals, including health policy goals.

While Canada continues to have a strong food safety system, with many positive attributes, the current food regulatory system must keep pace with changes in food microbiology, chemistry and nutrition, as well as in food product innovation and new food technology applications. Health Canada must also make improvements to manage challenges posed by shifts in the organization, scale, and orientation of the food industry so that regulatory standards can continue to have positive health protection and promotion impacts for Canadians.

Over the last few years, Health Canada has heard from a wide variety of stakeholders and partners, including other federal departments and agencies, P/T governments, industry associations, public interest groups, vulnerable sub-population groups, and individual Canadians, on a range of issues which they believe should be addressed through the modernization of Health Canada's food regulatory system. Recurring themes have included:

- ❏ Growing public, industry, and governmental awareness of the relationship between food safety and nutritional quality and chronic disease.

- ❏ The need for a robust and flexible food regulatory system that is capable of addressing the impacts of food globalization; trade liberalization and the internationalization of trade has become a significant food safety regulatory issue insofar as many foods available to Canadians are imported, or contain food components which originate from multiple countries – some of which have differing food safety assurance levels and systems. According to Agriculture and Agri-Food Canada (AAFC), Canada imported $22.4 billion worth of agri-food products in 2006 from 186 different countries – Canada's food regulatory system needs to be responsive to a widening range of potential risks and sources of risk.

- ❏ The need for increased efficiency, transparency, and predictability in the internal Health Canada processes used to manage applications for pre-market approval or notification.

- ❏ The need for an accessible and understandable food regulatory system that effectively manages and communicates risks to all Canadians.

- ❑ The need for a food safety system which is integrated and national in character, which provides food safety and nutrition assurances for all Canadians regardless of where they live, and which does not impede the development and trade of safe food products within and outside of Canada.

- ❑ The need for a responsive food regulatory system that can appropriately manage new risk management and risk communication issues, including:
  - ▸ Issues related to developments in the identification and detection of new bacteria, viruses, protozoan, prions, low-level environmental contaminants, natural toxins, etc.;
  - ▸ Issues related to the need for a responsive food regulatory system that can keep up with the pace of change and innovation. According to AAFC, agriculture and the agri-food industry's investment in research and development (R&D) has roughly tripled over the last 25 years, reaching almost $350 million in 2004; this has serious implications for food innovation related to new food product development, "functional foods" and foods with health claims, amongst other things that will come to Health Canada for evaluation.

REINFORCING HEALTH CANADA'S RISK-BASED FOOD REGULATION

There is general agreement that a risk-based approach to the regulation of food safety and nutritional quality is a good practice. It is for this reason that food products are subject to varying degrees of mandatory regulatory oversight, with some foods / food components being subject to strict controls at the pre-market level, and others being covered under general legislative provisions for food safety. The vast majority of food products available to Canadians are not subject to pre-market regulatory requirements. This is why an advanced understanding of risk management principles is essential to Health Canada as the department decides how and when a risk to the microbiological, chemical, or nutritional safety of the food supply necessitates governmental intervention to protect the integrity, safety, and security of the food on which Canadians rely.

Not only is this approach required for food regulation to be consistent with Canada's World Trade Organization (WTO) rights and obligations under the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, but it is also responsible government, using limited resources to effect maximum impact for the health of Canadians.

Health Canada uses a variety of risk management tools to meet its responsibilities under the *Food and Drugs Act* and the *Department of Health Act* – one of which is regulation. By modernizing Health Canada's regulatory toolkit, the Strategy can help to sustain the strengths of existing system, address gaps, and allow Canadians to continue to rely on the department's ability to appropriately target risks throughout the food continuum and intervene effectively and efficiently.

The table below outlines some examples of Health Canada risk management interventions along the food continuum, from pre-market to post-market interventions.

Table 1: Food Continuum and Examples of Health Canada Risk Management Interventions

Health and Safety Intervention Points	**Pre-Market Safety**	**Near-Market Safety**	**Market-Level Safety / "Real Time" Safety**	**Post-Market Safety**
Food Continuum Stages	Agricultural Production: includes animal husbandry, horticulture and crop development and management, seed development, animal and plant breeding, veterinary drugs and biologics	Food Processing: includes slaughter / abattoir, greenhouse harvesting, combining, milling, further processing related to mixing / adding / modifying food components or combining multiple foods	Food Retail: includes sale of pre-packaged foods, sale of bulk food, foods prepared at retail establishments, and also including health and safety as well as consumer protection labelling	Food Service and Food Disappearance: includes food served in restaurants, institutional settings, and in-home consumer food preparation and consumption
Identifying the Changing Food Safety Focus to Target Effective Risk Management	Food product or food application is still in a developmental stage prior to commercialization or "food" is planned, ie. is "unassembled" raw components	Food product is at the point of production (is being "assembled" but is still pre-retail in most instances	Food product is at the point of sale and is therefore available to all Canadians	Food product is in a consumer's home being prepared and consumed or is being served to a consumer and consumed.
Legislative and Regulatory Coverage **(*Food and Drugs Act* and *Food and Drug Regulations*)**	Sections 4 and 7 of the *Food and Drugs Act* Potentially applicable Divisions of the *Food and Drug Regulations*: 1, 16, 24, 25, 26, 28	Sections 4 and 7 of the *Food and Drugs Act* Potentially applicable Divisions of the *Food and Drug Regulations*: 1, 14, 21, 22, 23	Sections 4, 5, 6 and 7 of the *Food and Drugs Act* Potentially applicable Divisions of the *Food and Drug Regulations*: 1, 15, 27	Sections 4 and 7 of the *Food and Drugs Act* – does not apply to individuals in private settings
Examples of HC Role or Type of Intervention **(Regulatory functions and "Support for Regulatory Mandate" functions)**	Regulatory: - Requiring a regulatory submission for (and performing the safety evaluation of) a genetically-modified food or food additive or infant formulae prior to being allowed to be marketed - Assessing / evaluating the safety of pest control products and veterinary drugs to ensure safety of foods derived from subject plants and animals Support for Regulatory Mandate Activities: - Supporting development of a CFIA Code of Practice for the Hygienic Production of Sprouted Seeds	Regulatory: - Standards for undeclared food allergens - Developing new regulations to ban specified risk materials (SRMs) from entering the food supply to protect against mad cow disease Support for Regulatory Mandate Activities: - Research, advice, and guidelines for best practices in reducing pathogen load at the animal slaughtering stage, e.g. HACCP plans - Research, risk assessment, policy analysis and inter-agency work to coordinate approaches to the mitigation of the health harm associated with inadvertent introduction of undeclared allergens	Regulatory: - Mandating "Nutrition Facts Table" labelling to be on all prepackaged foods sold in Canada - Developing new regulatory maximum levels for harmful chemicals in foods - food allergen labelling requirements Support for Regulatory Mandate Activities: - Producing health risk Assessments (HRAs) for use by the CFIA in taking enforcement / emergency response actions – including food recalls	Regulatory: - Assessing the effectiveness of CFIA food safety programs (under *CFIA Act*) Support for Regulatory Mandate Activities: - dissemination of educational material and public service messages and health information products - Surveillance of dietary patterns to assess the exposure of Canadians to various chemicals and nutrients present in their food and to track foodborne illness

GOALS AND OBJECTIVES FOR A REGULATORY MODERNIZATION STRATEGY FOR FOOD AND NUTRITION

This discussion paper outlines five key goals for the Strategy, which focus on developing a set of modern regulatory tools to address new and longstanding food safety and nutrition challenges.

The goals of the Strategy are consistent with Health Canada's vision and mission, and support the critical success factors of the HPFB *Blueprint for Renewal II*, which are:

- ❏ A 21st century toolkit – legislation, regulatory frameworks and instruments;
- ❏ Internationally benchmarked regulatory practices, processes and risk management;
- ❏ A sustainable, high performance, science-based organization;
- ❏ Strategic international regulatory cooperation; and
- ❏ Enhanced partnerships and stakeholder involvement.

The goals, and the objectives for each, are a combination of potential responses to a range of short, medium, and long-term priorities. The Strategy is intended to work on two levels in parallel – the first, delivering concrete progress on food regulatory challenges linked to operational pressures on Health Canada in the short term, and the second, working on medium and longer-term commitments related to improving the contribution of the food regulatory system to population health.

GOAL 1: Improving Predictability, Effectiveness, Efficiency, and Transparency in Health Canada's Food Regulatory System

Health Canada's regulatory toolkit for food regulation is, in some instances, made up of tools, processes, and rules that were first established in the 1950s, 1960s, and 1970s. These tools and processes were established by government based on the state of science as it existed in those time periods. Needless to say, a great many things have changed since the *Food and Drug Regulations* were first promulgated. Many gaps in scientific knowledge have been partially or wholly filled by new research, while new knowledge and regulatory gaps have emerged in relation to new foodborne pathogens and contaminants, and in relation to nutritional value (and safety) of various food compounds.

Additionally, Health Canada's scientific data requirements for the evaluation of regulatory submissions may not always be clearly understood by petitioners, a situation that can be exacerbated when service standards for regulatory approvals or notifications may not be realistic given the number, type, and growing complexity of regulatory submissions received by Health Canada. It must be noted that not all regulatory considerations are within the department's control; Health Canada is also bound by federal policy on the development of regulations which requires significant consultations and which can create challenges of timeliness for the department as well as for petitioners.

In order for Health Canada to most effectively apply the principles of risk management there is a need to re-examine and modernize Health Canada's regulatory toolkit, and to look at the architecture of the *Food and Drug Regulations*, and the regulatory processes that emerge from that architecture, to ensure that regulatory interventions are proportional to risk.

Having the right tools and processes in place will enable the department to explain more clearly what it expects and requires from regulatees, will provide regulatees with a greater sense of predictability in managing their interactions with government, and will provide the basis for increased transparency and engagement with Canadians so that they can understand how food safety and nutrition risks are mitigated in the regulatory system.

Objectives:

1.1 Improve Health Canada's processes for pre-market regulatory clearances and notifications
- Examine ways of triaging / screening submissions to improve review times for straightforward requests and adapt best practices from other submission management models for the predictable, efficient, effective, and transparent management of pre-market submission processes under the *Food and Drug Regulations* (e.g. Division 16 (Food Additives), Division 25 (Infant Formulae and Human Milk Substitutes), Division 28 (Novel Foods))
- Developing realistic performance targets / service standards for pre-market regulatory processes.

1.2 Promote increased transparency throughout Health Canada's food regulatory risk assessment and risk management deliberations, including:
- Wider dissemination of food safety and nutrition surveillance data and analyses;
- Publication of Health Risk Assessments (HRAs);
- Examine new information dissemination to enable Health Canada to provide Canadians with more information about regulatory submissions;
- Publication of summaries of Health Canada regulatory decisions.

1.3 Explore the development of a new regulatory framework and new authorities for "Food Contaminants" under the *Food and Drug Regulations* in order to consolidate and clarify new and existing regulatory limits on contaminants in food.

1.4 Reform the regulatory architecture for food additives and develop a regulatory standard for "food grade chemicals" (or "food contact chemicals") under the *Food and Drug Regulations* by:
- Addressing longstanding pressures associated with the regulatory accommodation of food additives under the *Food and Drug Regulations*;
- Developing a food grade / food contact chemicals standard to be used by chemical manufacturers and retailers – which will establish safety limits for flavourings, processing aids, incidental additives, and food packaging materials that are used by the food processing industry.

1.5 Improve Health Canada's regulatory science capacity through expanded and appropriate international regulatory cooperation and work-sharing by:

- Developing agreements and arrangements with regulatory counterparts and multilateral organizations that are leaders in specific regulated areas;
- Continuing to promote Canadian interests and approaches internationally by participating in standards development in world standard-setting organizations such as the *Codex Alimentarius Commission*;
- Targeting worksharing activities that enhance the quality and efficiency of domestic decision making;
- Integrating international best practices in modernizing the regulatory system.

GOAL 2: Promoting Regulatory Responsiveness to Food Innovation and Promoting Consumer Access to Foods with Assessed Health Benefits

Health Canada has a mandate to protect and promote health with respect to the regulation of food; nothing in the Strategy is intended to change this mandate – Health Canada views the primacy of health protection in food regulation as non-negotiable. That being said, the pace of change within the food industry poses serious challenges for Health Canada as a regulator. Industry regulatees are seeking to be competitive in a globalized market place, and are seeking to respond to consumer demand for value-added food products, some with claims of added health benefit over and beyond basic nutrients and nourishment. Health Canada, as a science-based organization is expected to establish the scientific basis for the evaluation of permissible claims and new types of food products that may use technologies which have no prior history of safe use in Canada or abroad.

As a Government of Canada regulator, Health Canada is obliged to develop regulatory policy and approaches that are consistent with best practices in regulatory management as established by Treasury Board Secretariat of Canada and the Privy Council Office and to respect Canada's international treaty rights and obligations. As part of this commitment to due diligence, Health Canada must seek solutions to administrative and process-oriented obstacles to the market availability of food products which do not represent a risk to human health. Furthermore, Health Canada must contend with consumer demands for access to potentially health-enhancing food products, enabling informed choice to support increased consumer ownership over the management of their health. Health Canada must seek to find a balance between removing unnecessary operations-based obstacles against the more important needs of consumers to be assured of the truthfulness of health claims.

Objectives:

2.1 Developing a comprehensive framework for the management of food with health claims in order to accommodate food product innovation and related health claims, and to manage misperceptions/misunderstandings about the flexibility that may exist within the

current system, and to develop new regulatory and policy tools where deficiencies in the existing framework exist. This process would include:

- Improving stakeholder and public understanding of food with health claims;
- Establishing clear and consistent policies for health claims, including aligned policies for the management of the food / natural health product (NHP) interface;
- Examining the development of core nutritional criteria in the management of claims;
- Making improvements, as necessary, to the provisions of the *Food and Drug Regulations* dealing with permissible claims and standards of evidence;
- Protecting the credibility of reviewed/approved claims.

2.2 Complete the development of, and implement, a comprehensive policy on the discretionary fortification of foods.

2.3 Increase Health Canada's science and research capacity for health claims and food innovation by increasing strategic partnerships with academia, other branches / orders of government, and research centres and centres of excellence.

- e.g. Work collaboratively with the Research Branch of Agriculture and Agri-Food Canada (AAFC) in the conduct of a pilot project for specific health claims linked to soluble fibres.

GOAL 3: Modernizing the Regulatory Toolkit to Address "Food Contributors" to Chronic Disease

Some analytical estimates, based on the Economic Burden of Illness in Canada (EBIC) report (http://www.phac-aspc.gc.ca/publicat/ebic-femc98/index.html), have suggested that the total cost of cardiovascular disease alone is roughly $18.5 billion every year in direct healthcare costs and indirect losses in productivity. Furthermore, health sequelae linked to foodborne pathogens and the presence of low-levels of genotoxic carcinogens in the food supply also play important roles in shaping the profile of chronic disease in Canada. While it is true that there is a wide range of factors contributing to chronic disease – including lack of physical activity and unhealthy lifestyle choices such as tobacco and alcohol use – there is a health policy need for the food regulatory system to be able to respond more robustly to the food and diet contribution to chronic disease risk.

The relationship between food safety and nutrition, obesity, and chronic diseases such as Type-2 Diabetes, celiac disease, osteoporosis, and cancer are important challenges for the scientific and regulatory communities within government, and represent another avenue by which Health Canada can look to influence health outcomes. Health Canada has experience in ensuring certain essential nutrients and minerals are present in the food supply to support healthy development (e.g. iodine in salt, certain vitamin fortification standards – including Vitamin D in milk for example). However, the department's regulatory toolkit has generally not been used to address components of foods that are associated with increased risk of chronic disease, and the role that food and diet can play in either exacerbating or reducing chronic disease.

In looking at ways for the food regulatory system to better address "food contributors" to chronic disease, the Strategy proposes to build on a variety of public reports[5] which discuss population health and provide recommendations for the regulatory management of Canada's food supply.

Objectives:

3.1 Develop strategies to reduce the presence of trans fatty acids in Canadian diets to the lowest possible levels, consistent with the reduced levels of trans fats recommended by the Trans Fat Task Force.

3.2 Develop effective risk management approaches to reduce Canadian dietary exposure to low-level genotoxic carcinogens and other trace contaminants in food – whether these originate from environmental sources or are food processing-induced, examples include acrylamide, dioxins, furans, benzene, etc.

3.3 Develop effective strategies for the use of Health Canada's food regulatory levers to address the chronic medical conditions of vulnerable sub-populations and factors which contribute to these conditions. Early work should focus on:
- Celiac disease; and
- Food allergens.
- *Also see Goal 4 / Objective 4.2*

3.4 Contribute to the science base regarding risks of chronic disease development associated with incidental exposure to bacteria, protozoan, parasites, viruses, and prions.

GOAL 4: Improving Health Canada's Responsiveness to Acute Food Safety Health Risks – Responding to New Threats While Managing Ongoing Risks

The food regulatory modernization initiative must remain seized of the impact of acute foodborne illness on Canadians, with the latest figures estimating between 11-13 million cases of gastro-intestinal illness per year. Some analytical estimates put the burden of acute foodborne illness at over $1 billion a year in direct healthcare costs and indirect losses in productivity. As an example, events related to microbial contamination of lettuce and other

[5] Examples of public reports which address population health including references to food and nutrition (non-exhaustive):
- "*Eating Well with Canada's Food Guide*" (Canada's Food Guide / Health Canada revisions) (2007)
- "*A New Perspective on Health for Canadians*" (The Lalonde report) (1974);
- "*Royal Commission on the Future of Healthcare in Canada*" (Romanow Commission Report) (2002);
- "*The Health of Canadians – The Federal Role*" (The Kirby Report) (2002);
- "*Report to Canadians 2005 – Accelerating Change*" (Health Council of Canada annual report) (2005).
- "*A Health Outcomes Report - Why Health Care Renewal Matters: Lessons from Diabetes*" (Health Council of Canada, 2007)

produce in the United States over the last 6 months have shown how easily microbial safety at the farm level can impact on a wide geographic area and create real public health risks.

Acute foodborne illness is a difficult and complex challenge insofar as foodborne contamination can occur throughout the entire food continuum (from farm-level all the way up to the consumer) and the health effects of foodborne illness can be very serious for the health of Canadians – in some cases leading to death. In addition, in Canada, responsibility for responding to foodborne illness is shared among a number of regional, P/T governments and federal partners. It is in this context that Health Canada needs to find ways of fully exercising its mandate to protect and promote human health as it relates to food. This will increase the department's flexibility and influence in preventing, preparing for, and responding to risks associated with food contamination.

Furthermore, there is a need to have a food regulatory system that is prepared and positioned to respond to new and emerging food safety threats to Canadians and to the integrity, safety, and security of Canada's food supply and agri-food production systems. In this context, the Strategy is also intended to help the department effectively balance the need for HC action on more common food contamination problems, while appropriately responding to emerging threats related to new strains of harmful bacteria, botulism, environmental chemicals (e.g. PCBs, dioxins, etc.), viruses, natural toxins, prions, and potential bioterrorism agents (chemical, biological, radiological, and nuclear (CBRN)) as well as compounds which are, or are linked to, food allergens.

This goal also requires Health Canada to adopt a more comprehensive approach to risk communications (for acute and chronic disease risks) and to make improvements in the production and analysis of health intelligence and surveillance information and in the development of approaches to vulnerability and threat assessment.

Objectives:

4.1 Expand Health Canada Food Program coverage of new and emerging pathogenic / contaminant agents which threaten human health and which are capable of using food as a vector.

4.2 Enhance the effectiveness of risk communications for food safety and nutrition risks, consumer-level education, and retail-level food labelling for improved public health and consumer protection, including:

- Completion and implementation of a comprehensive food allergen labelling policy;
- Completion and implementation of regulations for safe handling labelling for raw ground meats;
- Build on the *Fight*BAC!™ education model that was developed collaboratively through the Canadian Partnership for Consumer Food Safety Education (CPCFSE) to broaden the range of information sources available to Canadians regarding foodborne risks;
- Develop a comprehensive risk communication strategy for chemical contaminants and microbial risks;

- Strengthened collaboration with health promotion authorities to improve consumer understanding of nutrition labelling information and to be more effective in communicating nutritional safety risks to Canadians.

4.3 Improve Health Canada's emergency preparedness and the department's capacity to provide emergency response assistance vis-a-vis food defence and food safety, including:

- Strengthening HC/CFIA emergency management collaboration for:
  - Laboratory cooperation.
  - Rapid identification and detection methods development for non-traditional and exotic pathogens and contaminants.
- Fulfilling Health Canada's bioprotection commitments under the *Security and Prosperity Partnership (SPP) of North America* to identify and address food defence vulnerabilities within Canada/North America's food production systems – moving on priority security gaps first, including:
  - Vulnerability and threat assessment for priority food production systems;
  - Canada-US joint risk management strategy for the safety of imported foods against intentional contamination threats;
  - Improving Canada-US laboratory cooperation for food safety and food defence emergency response issues;
- Expand research and modelling work supporting the development of methods of identification and detection for Chemical, Biological, Radiological, and Nuclear (CBRN) threat agents in food.
  - Continue to participate in the Chemical, Biological, Radiological, and Nuclear (CBRN) Research and Technology Initiative (CRTI) through Defence Research and Development Canada (DRDC).

4.4 Improving Health Canada's ability to produce, analyze, and use health/medical intelligence and surveillance information to manage food safety risks and outbreaks.

GOAL 5: Promoting a Sustainable and Integrated System for Food Safety and Nutrition in Canada

Canada's food safety system is the product of an array of collaborative activities which take place between multiple jurisdictions – both between and within different orders of government. Health Canada's regulatory standards for food safety and nutrition are an important contribution to that much larger system. In considering the food safety system at a macro-level, it is clear that the effectiveness of Health Canada's food safety and nutrition regulatory standards in protecting health is significantly impacted by the extent to which these standards are consistently applied to all food sectors across the country.

Food regulatory modernization must strive to maximize the value of the department's contribution to national food safety. A sustainable and integrated system that improves the

consistent application of Health Canada's food safety and nutrition standards and promotes the effectiveness of F/P/T risk management programming is in the interests of all Canadians.

Objectives:

5.1 Improve the alignment of food safety and nutrition priorities and risk management approaches within Canada's food safety system by strengthening and deepening collaboration between Health Canada, the CFIA, the Public Health Agency of Canada (PHAC), and the food safety authorities in the Provinces and Territories (P/Ts).

5.2 Providing effective science-based risk management advice to the CFIA, the food industry, and P/Ts with respect to the potential value of non-mandatory food safety enhancement programs (FSEPs), e.g.:

- Hazard Analysis Critical Control Point (HACCP) plans;
- Commodity specific codes of practice for food hygiene;
- Industry-initiated self-regulation efforts to go beyond Federal food safety requirements.

NEXT STEPS

Health Canada anticipates:

- ❏ Engaging a broader range of stakeholders to discuss Health Canada's goals and objectives under the Regulatory Modernization Strategy for Food and Nutrition.
- ❏ Further clarifying the scope and scale of the Strategy through public, stakeholder, and inter-agency consultations.
- ❏ Publishing the Strategy.

COMMENTS OR QUESTIONS?

Comments and/or questions on the *Regulatory Modernization Strategy for Food and Nutrition* should be directed to:

Address:

Director, Bureau of Food Policy Integration, Food Directorate,
Health Products and Food Branch, Health Canada,
Centre de recherche Sir Frederick Banting Research Centre, Tunney's Pasture,
Address Locator: 2202E
251 promenade Sir Frederick Banting Driveway,
Ottawa, Ontario.
K1A 0K9

Fax: (613) 946-4590

Email: bfpi@hc-sc.gc.ca

ANNEX

Background: The *Food and Drugs Act* and the *Food and Drug Regulations*

The Federal Minister of Health is empowered to make regulations that may be required to assure the safety and nutritional value of all foods sold in Canada as this task relates to preserving and promoting the health of Canadians. Health Canada is responsible for establishing standards for the safety and nutritional quality of all foods sold in Canada. Health Canada exercises this statutory mandate under the authority of the *Food and Drugs Act*, and pursue its regulatory mandate under the *Food and Drug Regulations*, and the *Department of Health Act*. Additionally, the Minister of Health is also responsible, under Section 11(4) of the *Canadian Food Inspection Agency (CFIA) Act*, for assessing the effectiveness of the Canadian Food Inspection Agency (CFIA) with respect to food safety. Health Canada is also responsible for the establishing maximum residue limits for agricultural chemicals and veterinary drugs.

The *Food and Drug Regulations* are the legal tool, under the *Food and Drugs Act*, through which Health Canada establishes regulatory standards for the safety and nutritional quality of Canada's food supply. All health and safety standards under the *Food and Drug Regulations* are enforced by the CFIA, which is also responsible for the administration of other non-health and safety regulations relating to food.

The *Food and Drug Regulations* elaborate on the legislative requirements of Sections 4, 5, 6, and 7 of Part I of the *Food and Drugs Act*, which require food producers selling product in Canada to produce/manufacture, advertise, label, and sell food which is safe for human consumption and which comply with regulatory standards for health, safety, and consumer protection.

Within the *Food and Drug Regulations* food standards are divided into categories called "divisions". There are 28 Divisions in the main body of Part B (Food) of the *Food and Drug Regulations*. The *Food and Drug Regulations* also contains 3 Divisions in Part D (Vitamins, Minerals, and Amino Acids), Part E (Cyclamate and Saccharin Sweeteners), as well as a number of separate schedules" which are used to help create health and safety food standards and serve as regulatory reference points for allowable limits of particular substances/compounds.

Food and Drug Regulations

Part B (Foods)

Division 1: General Provisions (including labelling)
Division 2: Alcoholic Beverages
Division 3: Baking Powder
Division 4: Cocoa and Chocolate Products
Division 5: Coffee
Division 6: Food Colours
Division 7: Spices, Dressings, and Seasonings
Division 8: Dairy Products
Division 9: Fats and Oils
Division 10: Flavouring Preparations
Division 11: Fruits, Vegetables, Their Products and Substitutes
Division 12: Prepackaged Water and Ice
Division 13: Grain and Bakery Products
Division 14: Meat, Its Preparations and Products
Division 15: Adulteration of Food
Division 16: Food Additives
Division 17: Salt
Division 18: Sweetening Agents
Division 19: Vinegar
Division 20: Tea
Division 21: Marine and Fresh Water Animal Products
Division 22: Poultry, Poultry Meat, Their Preparations and Products
Division 23: Food Packaging Materials
Division 24: Foods for Special Dietary Use
Division 25: Infant Formulae and Human Milk Substitutes
Division 26: Food Irradiation
Division 27: Low-Acid Foods in Hermetically-Sealed Containers
Division 28: Novel Foods

Part D (Vitamins, Minerals, and Amino Acids)

Division 1: Vitamins in Foods
Division 2: Mineral Nutrients in Foods
Division 3: Addition of Vitamins, Mineral Nutrients, or Amino Acids to Foods

Part E (Cyclamate and Saccharin Sweeteners)

- Sale
- Advertising
- Labelling

Applicable Schedules (excluding Schedule A)

Schedule K: Reasonable Daily Intake for Various Foods
Schedule L: Nutrition Facts Table Format
Schedule M: Reference Amounts