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# Health Canada's Regulatory Modernization Strategy for Food and Nutrition (RMSFN)

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Canada 

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## INTRODUCTION

In April 2007 Health Canada's Health Products and Food Branch (HPFB) released its Blueprint for Renewal II 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.

Blueprint for Renewal II recognizes the important challenges facing Canadians and the Canadian food production chain. Few governmental tasks are as central to the everyday lives of Canadians as the responsibility it shares with partners to maintain the safety and nutritional quality of the food supply. It is critically important that Health Canada's regulatory system for food and nutrition be able to respond to new challenges – irrespective of their origin - with effective approaches that can help Canadians maintain and improve their health. 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”*

## WHY MODERNIZE? 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. 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 modernize to keep pace with changes in science and technology, including 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 help protect and promote the health of 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 a growing awareness of the relationship between food safety and nutritional quality and chronic

disease; the need for a robust, integrated, responsive and flexible food regulatory system that is capable of addressing the impacts of globalization and managing emerging issues; and the need for increased efficiency, transparency, and predictability in Health Canada's management of pre-market submissions for food products.

#### **WHAT WE HEARD FROM STAKEHOLDERS**

In May 2007, the Food Directorate released its discussion document, "Towards a Regulatory Modernization Strategy for Food and Nutrition" (the Strategy) which outlined a vision and plan for modernizing the regulatory system for food. At the same time, an on-line consultation was launched to seek the views of stakeholders on the Strategy. A summary of the comments received during the consultation is available on Health Canada's website.

In general, participants were in agreement with the Strategy, emphasizing that the modernization strategy was timely, and needed to address the evolving challenges around food safety, product innovation, and global markets. Improving predictability, efficiency and transparency of the system was seen as a key goal.

There was support for Health Canada to continue to meet its responsibilities under the Food and Drugs Act with a modernized toolkit that sustains the strengths of the existing system but employs an appropriate mix of risk based approaches: this would continue to promote and protect health while avoiding unnecessary impediments/burden to industry. At the same time, there was an emphasis on ensuring that modernization efforts remained grounded in science based risk assessments.

Some gaps were noted by participants. In particular, it was noted that the modernization efforts did not appear to reflect appropriately the integration of other departments/agencies and partners who share responsibility in the delivery of the food safety system.

Participants remarked that for this initiative to be successful, sufficient resources would need to be assured to help move improvements beyond the consultation stage.

#### **THE REGULATORY MODERNIZATION STRATEGY FOR FOOD AND NUTRITION - A REVISED FRAMEWORK**

The important feedback received has been reflected in a revised Regulatory Modernization Strategy. This revised strategy aligns, as well with other recent government initiatives, the Government of Canada Food and Consumer Safety Action Plan being foremost among these.

In January 2008, the Food and Consumer Safety Action Plan (the Action Plan) was published targeting the transformation of the government's approach to product safety. The Action Plan is composed of a series of initiatives to modernize and strengthen Canada's safety system for food, health and consumer products. The three pillars of the Action Plan focus on active prevention (instead of primarily reacting to problems), targeted oversight to areas of highest risk, and rapid response when a potential problem arises.

The Action Plan builds on the fundamental principle that product safety, including food, is a shared responsibility among government, industry and consumers, and that each group needs

to have the appropriate information and tools in order to play their role effectively. With respect to food, the Action Plan notes that modernizing the food safety system to meet the new risks and challenges requires integrated, proactive approaches. It needs to provide “new and better information on food risks in the Canadian marketplace, and involve industry and Canadians to address those risks”. Further, the Action Plan recognizes the need to enhance policies, standards and processes as well as collaborate with international partners, to strengthen the prevention of food safety issues.

The revised Strategy confirms Health Canada's commitment to strengthening prevention and risk based regulation, working with partners to enhance the safety and nutritional quality of the food supply, and providing consumers with information for informed decision making

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

The Strategy's five goals focus on developing a set of modern regulatory tools to address current and emerging food safety and nutrition challenges and are consistent with Health Canada's vision, mission and support the critical success factors of the HPFB Blueprint for Renewal II, which are:

- A 21<sup>st</sup> 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 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 One: 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. Although many gaps in scientific knowledge have been partially or wholly filled by new research, new knowledge and regulatory gaps have emerged and continue to emerge as new foodborne pathogens and contaminants are discovered and the nutritional value (and safety) of various food compounds are identified.

The very nature of our food supply has also changed 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. This has resulted in the emergence of common challenges and issues in the international community, both for

governments and for industry. Capitalizing on the experiences and approaches of other jurisdictions and adapting best practices to the Canadian context is important if we are to improve our regulatory system for food and nutrition.

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 of industry in order to meet regulations and policies, will provide 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 submissions;
  - Examine ways to improve communications between Health Canada and petitioners to facilitate a more efficient, effective and transparent process; and,
  - Develop service standards and performance targets for pre-market review activities.
  
- 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; and,
  - 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:
  - Address longstanding pressures associated with the regulatory accommodation of food additives under the *Food and Drug Regulations*; and,
  - Develop 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:

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

**GOAL Two: 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 above 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:

- 2.1.1 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; and,
- 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.

### **GOAL Three: Modernizing the Regulatory Toolkit to Address “Food Contributors” to Chronic Disease**

Some analytical estimates, based on the Economic Burden of Illness in Canada report, 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 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 among 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<sup>1</sup> 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.
- 3.4 Contribute to the understanding of risks of chronic disease development associated with incidental exposure to bacteria, protozoan, parasites, viruses, and prions.

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

The impact of acute foodborne illness on Canadians is significant, 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. Recent high profile food safety events both in Canada and internationally demonstrate the global nature of concerns in this area.

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. While the focus of Health Canada is to prevent foodborne

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<sup>1</sup> 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)

illnesses as much as possible, when problems do arise, it is critical that response be rapid and effective. In Canada, responsibility for responding to foodborne illness is shared among a number of regional, Provincial-Territorial governments and federal partners. It is essential that the tools and processes are in place to allow Health Canada to work with its partners 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). This is needed so that consumers have the information they need to make informed food choices, and can play their role effectively in the food safety system.

Objectives:

- 4.1 Enhance/Optimize Health Canada's rapid response to potential food safety risks by:
  - working with partners (federal and provincial governments, industry) to strengthen the efficiency and effectiveness of collaborative response in the event of potential emergency/outbreak situations, including reviewing and clarifying: roles and responsibilities, response protocols, standard operating procedures, communication protocols;
  - strengthening collaborative processes around the provision of Health Canada health risk assessments to CFIA during recall investigations (including establishing performance targets and reviewing SOPs); and,
  - enhancing foresight and early warning through development of improved tools, and integration in international information networks.
  
- 4.2 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.
  
- 4.3 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;
  - Develop approaches for safe handling labelling for raw ground meats;
  - Build on the "Be Food Safe" campaign and the *FightBAC!*<sup>TM</sup> 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;
- Strengthened collaboration with health promotion authorities to improve consumer understanding of nutrition labelling information (including the contribution of the ingredient list) and to be more effective in communicating nutritional safety risks to Canadians; and,
- Strengthen and streamline collaborative communications approaches to consumers during potential emergency/outbreak situations.

### **GOAL Five: 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, (domestically and internationally), and include critical roles along the food value chain for government, producers, industry and consumers. Health Canada's regulatory standards for food safety and nutrition are an important contribution to that much larger system. In considering the larger food safety system 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 is needed that works with partners in the food safety system to identify the areas of greatest risk and collaboratively develop the most appropriate strategies to reduce these risks

#### 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), Agriculture and Agri-Food Canada (AAFC) and the food safety authorities in the Provinces and Territories (P/Ts).
- 5.2 Improve the early development and implementation of most appropriate preventative measures in the food safety system by working with partners (federal government, P/T, internationally, industry and stakeholders) to enhance the identification and understanding of emerging and existing food borne hazards, and to develop effective intervention strategies and tools that will help reduce risks to human health.

#### **MOVING FORWARD**

The Strategy, the Action Plan, and the stakeholders' comments are essential elements of the Food Directorate Strategic Plan 2009/2014. The Strategic Plan will articulate a broader vision and change agenda for the Directorate over the next five years and is targeted for publication in Spring 2009.