Food Directorate Health Products and Food Branch Health Canada

First Annual Report on Program Priorities & Achievements

2003-2004

Dear Colleague, Food Safety & Nutrition Community

I am pleased to share with you the 2003-2004 program priorities and achievements for the Food Directorate of Health Canada. The attached document gives an overview of the strategic priorities and key activities of the Food Directorate for this fiscal year (April 1, 2003 - March 31, 2004), and outlines some of our key achievements over the last fiscal year.

We have identified initiatives which we are committed to for this fiscal year, considered our "Alist," and a "B-list" of priorities, other important work which must also be undertaken, but not necessarily with key milestones this year. The A list focuses in the main on current key issues, with specific deliverables, while the B list relates mostly to our ongoing work.

The strategic priorities in this document were the result of comments received from our consultation sessions with interested parties inside and outside the Food Directorate in 2002, as well as input from other parties over the past months. I wish to emphasize my intention to continue to work with interested parties in identifying and addressing food safety and nutrition issues.

We thank you for your continued support and look forward to working with you in the future.

Karen L. Dodds, Ph.D. Director General Food Directorate

Introduction

Responsibility for food safety in Canada is shared by a number of departments and agencies at the federal, provincial/territorial, and municipal levels. Federally, Health Canada and the Canadian Food Inspection Agency (CFIA) have key responsibilities relating to health and safety. Agriculture and Agri-Food Canada (AAFC) helps the agri-food sector identify and address a broad range of issues, including food safety.

Much of Health Canada's focus on food safety is coordinated by the Food Directorate of the Health Products and Food Branch. In support of Health Canada's mission to help Canadians maintain and improve their health, the Food Directorate is the federal health authority responsible for establishing policies, setting standards and providing advice and information on the safety and nutritional value of food.

The work of the Directorate addresses chemical and microbiological hazards in the food supply as well as the nutritional safety and value of food. The Directorate has some 400 employees across the country, including scientists and technicians who perform a variety of specialized activities to maintain and improve the high quality of food Canadians have come to enjoy and expect.

The authority of the Food Directorate comes mainly from the *Food and Drugs Act* and Regulations, the *Canadian Food Inspection Agency Act*, and the *Department of Health Act*. The Food Directorate undertakes pre-market review of certain food products such as food additives and genetically-modified foods, research, surveillance, policy development, standard-setting, and risk assessment. As well, the Food Directorate assesses the effectiveness of the activities of the Canadian Food Inspection Agency¹ related to food safety.

New food safety issues occur with regularity. This year the most important related to our work in response to the finding of the cow in Alberta that was positive for bovine spongiform encepalopathy (BSE). This led to the revision of our policy protecting Canadians from BSE and other TSEs. We will continue our work on this issue in order to maintain policies and regulations which will help to ensure a safe food supply and inspection system.

The CFIA, which reports to the Minister of Agriculture and Agri-Food, provides all federal inspection services related to food safety, economic fraud and trade-related requirements. The CFIA is responsible for the enforcement of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* as they relate to food, and the administration of the provisions of the *Food and Drugs Act* that do not relate to public health, safety and nutrition. The Agency is also responsible for the administration and enforcement of other food legislation including the *Meat Inspection Act*, the *Fish Inspection Act* and the *Canada Agricultural Products Act*.

New Government-wide initiatives have provided some new opportunities and challenges for the Food Directorate. The recently announced Agricultural Policy Framework will provide us with some new resources for work in the area of on-farm food safety policies and standards. Smart Regulations is an initiative that encompasses all regulatory areas.

This document outlines our strategic priorities in fulfilling our mission, describes our areas of work over the fiscal year with focus on some specific priorities, presents some recent key activities and achievements, and highlights some challenges and new priorities in realizing Food Directorate's vision of becoming "the most trusted authority providing policies, standards, advice and information on the safety and nutritional value of food."

Strategic Priorities

Based on input from a wide variety external stakeholders at national consultation sessions held in 2002, as well as input from our staff, the Food Directorate has developed six strategic priorities.

1) Communications, Consultation and Education

Undertaking solid communications, consultations and education initiatives was one of the most important, and certainly the most consistent, theme raised in our discussions across Canada. We are committed to being a more participative, open and transparent program, encouraging involvement of the Canadian public, industry stakeholders, and government departments, in decisions concerning food safety priorities, policies and programs. We are also committed to improving our communication and education practices. We will strive to ensure that all of our health information is based on factual scientific data and research and to improve our risk communication practices in such a way as to help the public make informed health choices.

2) Surveillance and Food Monitoring

Surveillance and food monitoring is a key priority of the Food Directorate. We understand the importance of identifying chemical and microbiological contaminants in the food supply and conducting the appropriate scientific research and analysis. We intend to work with stakeholders in the area of food contaminant analysis towards the development of a national food contaminant surveillance program. We will also work with our many partners towards coordinated food, nutrition and total-diet surveys.

3) Management of Risks for Vulnerable Groups

There is particular need to enhance the management of risks for vulnerable populations, including seniors, persons with compromised immune systems and especially children. The Food Directorate understands the importance of protecting vulnerable populations and will also work with others to create policies supporting healthy eating practices among vulnerable groups.

4) Emergency Preparedness and Response

The food safety system in Canada needs to be prepared to respond to threats of food terrorism. As such, we need to collaborate with CFIA to develop and improve protocols to deal with food-related disease outbreak investigations and recalls of a food product for which the threat of food terrorism exists. We are working on the rapid detection of chemical and microbiological agents that could be a threat if delivered through contaminated food or water. In addition, the Food Directorate will work to improve the communication network between governments, industry and consumers of any food-related emergency.

5) Research and Risk Management Strategies along the Food Continuum

In support of the Government's Agricultural Policy Framework, the Directorate will collaborate with industry, CFIA and AAFC on standards, policies and interventions to address food hazards at all levels of the food chain, most notably on the farm. As well, we will undertake related research. Working at all levels of the food chain will allow us to improve our strategies for food safety.

6) Responding to Food Innovation

Across all the regions there was uniformity regarding four important issues surrounding foods derived from new technologies: 1. *Research*; 2. *Evaluation*; 3. *Regulation*; and, 4. *Communication*. This applies to our work on functional foods and related product-specific claims and to the safety assessment of novel foods and products of biotechnology (genetically modified foods). The Food Directorate intends to review, develop and implement transparent policies and procedures to improve the safety assessment of foods derived from new technologies.

Areas of Work (2003-2004)

We organize our work according to certain core activities: policy and regulatory development; premarket evaluation and risk benefit assessment; research and surveillance; health outcomes; and, management and administration. In order to maintain a relatively balanced program in an area where urgent pressures are common, we set specific portions of our operating budget for each activity. In 2003-04, 45% has been provided to Research and Surveillance, 25% to Policy and Regulatory Development, 10% to Premarket Evaluation and Risk Benefit Assessment, 5% to Health Outcomes, 15% to Management & Administration. We also organize our work by Project Area².

Food Directorate management has identified 27 discrete areas of food safety and nutrition within which we work (e.g., chemical contaminants, high-risk food-borne pathogens, nutritional quality). All scientific work done in the Directorate relates to one of these (refer to Annex - Food Directorate Project Areas).

Within these areas, several projects have emerged as key priorities for 2003-2004. These are shown in the tables below. In order to distinguish between what we are committed to for this fiscal year and other important work which must also be given consideration, we have identified our "A-list" and "B-list" of priorities. The A list focusses in the main on current key issues, while the B list relates mostly to our ongoing work.

The A List

Policy/Regulatory Development

Activity	Milestones	Project Area
For all activities, improve our consultation, communication and education efforts		All
Policy Development in Bovine Spongiform Encephalopathy (BSE)	Develop policy to protect human health - New regulations, published in Canada Gazette Part II, July, 2003. Support CFIA, AAFC, industry in development of risk management options - animal feed, surveillance - by March, 2004.	TSE's (includes BSE)
Regulatory development and review of policy on addition of Vitamins and Minerals to food.	Final proposed policy published in January 2004. Proposed regulations published in Canada Gazette, Part I, in spring 2004.	Nutritional Quality and Safety
Regulatory development for labelling of priority food allergens.	Final proposed policy published in January 2004 Proposed regulations published in Canada Gazette, Part I, in spring 2004	Food Allergens
Food Irradiation policy development.	Summary of comments and responses posted in January 2004. Workshop re outstanding issues in spring 2004. Decision on regulatory proposal by summer 2004	Food Irradiation
Safety labelling of raw meat and poultry	Consultation with stakeholders early 2004	Highest risk food- borne pathogens

Activity	Milestones	Project Area
Revision of guidelines on Listeria in Ready-to Eat Foods.	Publish revised policy in January 2004	Highest risk food- borne pathogens
Finalize proposals for revised regulations for bottled water and prepackaged ice	Proposed regulations published in Canada Gazette, Part 1, by March 2004	Highest risk food- borne pathogens Trace Toxic Elements
Revisions to Food Additive Regulations	Consultation in early 2004 on proposed approach. Publication in Canada Gazette, Part 1 in FY 2004-05	Food additives
Education of stakeholders, partners and industry of the new nutrition labelling regulations (published January 2003).	FAQs posted on website. CD-ROM available March 2004 with a "how-to" guide for calculating available display space and different formats	Nutrition Labelling and Nutrient Content Claims
Policy development for genetically modified and other Novel Foods	Revise Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms - Fall 2003 Respond, with other government departments, to CBAC Report in early 2004	Novel Foods
Contribute to Health Canada's health protection legislation initiative	Thematic Consultation session on Food - date to be confirmed in early 2004	Regulatory Development

Evaluation and Risk Benefit

Activity	Milestones	Project Area
Effective, efficient and timely premarket evaluation of industry submissions - novel foods, food additives, food packaging materials, infant formulas, etc.	 Evaluations keep pace with submissions Improve our pre-market evaluations by strengthening the use of quality management principles and practices 	Various
Complete health risk assessments related to the chemical and microbiological safety and nutritional value of foods.	- Respond in a timely manner based on risk-based priority	Various

Intelligence (Research and Surveillance)

Project Area	Activity
Food and Nutrition Surveillance	Work with Statistics Canada and other areas of Health Canada to implement the second cycle of the Canadian Community Health Survey (CCHS), a survey intended to provide reliable, timely information about dietary intake and nutritional well-being.
Food and Nutrition Surveillance	With stakeholders, enhance the "Canadian Nutrient File", a standard reference food composition database reporting the amounts of nutrients in foods commonly consumed in Canada and consider related databases.
Food and Nutrition Surveillance	Total Diet Study and Child Health Surveillance Initiative - survey and analysis of various food products from various supermarkets across Canada, particularly, retail baby food and infant formula for potential toxicants, trace elements such as mercury and total fat and fatty acid composition through
Food and Nutrition Surveillance	Creation of a national surveillance program to identify an inventory of federal, provincial and territorial food surveillance and monitoring activities for veterinary drug residues in foods.
Food Allergens	Develop methodologies for allergen testing in processed foods, determining threshold levels and sensitivity of individuals to allergens.
Organic Chemical Contaminants	Evaluation and implementation of new analytical screening procedures for more rapid detection of acrylamide in food.
Organic Chemical Contaminants	Determination of persistent organic pollutants (POP's) in foods and assessment of the immunotoxicity of food contaminants
Highest risk food-borne pathogens	Quantitative Risk Assessment of Salmonella, Listeria and Verotoxigenic E. coli in foods
Highest risk food-borne pathogens	Research on incidence of <i>Listeria monocytogenes</i> in foods, as well as virulence factors, minimum infectious dose, molecular typing and characterization.
Highest risk food-borne pathogens	Analysis of rapid methods, development of new and improved methods for the isolation and detection, and risk assessment of <i>Campylobacter spp</i> . and <i>Salmonella</i> in foods and environmental samples

Policy/Regulatory Development

The B List

Activity	Project Area
Review final drafts of generic health claims on the relationship between fat and cancer and between fruit, vegetables, whole grains and brans and heart disease.	Functional Foods and Health Claims
Make amendments to the Food and Drug Regulations to establish a framework to permit the product-specific authorization of health claims and product categorization of foods	Functional Foods and Health Claims
Policy Development in Infant Formulas	Nutritional Quality and Safety
Continued policy development on caffeine addition to foods.	Natural toxins/food components/food additives
Policy Development in Dioxins, Furans and Dioxin-like PCB's	Organic Chemical Contaminants
Policy Development in raw foods of animal origin and raw foods of plant origin	Highest risk food-borne pathogens

Health Outcomes

Project Area	Activity
Program Evaluation	Implementation of a performance measurement framework within the Food Directorate to assess how our programs are meeting our mandate and priorities.
Food Safety Assessment	Food Safety Assessments of various CFIA programs (QMP Assessment - Spring 2004, Dairy Assessment - Fall 2004)

Management & Administration

In addition to our regular management and administration activities, this year we intend to embark upon a uniform approach to Quality Management throughout the Food Directorate. We will build upon our work of integrating quality systems management throughout our activities and programs. We will also continue to improve our Program Management and Reporting System, a database containing all of our work, and links our projects to programs and priorities and funding.

Achievements from 2003

Listed below is a sample of recent and ongoing Food Directorate highlights:

Nutrition Labelling & Generic Health Claims

On January 1, 2003, new regulations on nutrition labelling were published. These regulations make the provision of more nutrition information in a standard format mandatory on most packaged foods helping Canadians to make better informed healthful eating choices

Food Irradiation Consultation Sessions

We held information and consultation sessions in eight cities across Canada to provide Canadians with an opportunity to present their views, and for us to receive comment and input, on proposed amendments to the Food and Drug Regulations to extend the use of Food Irradiation to four new commodities: ground beef, poultry, shrimp and prawns and mangoes.

Vitamin and Mineral Addition to Foods

Health Canada's *Addition of Vitamins and Minerals Policy Review and Implementation - Consultation Document* was released for stakeholder comment in November 2002. The proposed policies are intended to aid in maintaining and improving the nutritional quality of the Canadian food supply, and preventing nutrient deficiency diseases in the general population and in selected groups, as well as permitting a wider distribution of vitamins and minerals in the food supply to enhance consumer choice. Since the Stakeholder Consultation in November, we have considered different approaches to the potential new category of discretionary fortification and held a targetted consultation on that issue in June, 2003.

Safe handling of raw ground meat

The Health Canada education campaign continues across the county through ongoing publication of food safety messages in local newspapers. The food safety messages, also distributed on fridge magnets to consumers that could be at high risk, focus primarily on the need to use a thermometer when cooking ground beef, and promote the slogan "Your Burger's Done at 71". In addition, we have continued to promote the messages of the ongoing Fight Bac! campaign: clean, separate, cook and chill.

Foods derived from Biotechnology / Novel foods

Significant progress has been made in the area of foods derived from biotechnology and novel foods. We continue to support and work with the Canadian General Standards Board to solidify standards of voluntary labelling of genetically modified foods including meaningful criteria for labelling, understandable messages for consumers, and a consistent policy to verify the truthfulness of labels. Revised draft Guidelines for the Safety Assessment of Novel Food have been prepared. These draft Guidelines and issues related to the regulation of novel foods, were the subject of recent consultation.

Chemical Contaminants

The Food Directorate has been considering how we can bring a more comprehensive collaborative approach to the surveillance of foods for chemical contaminants with other parties. We initiated this process of better coordination of food surveillance activities for chemicals at a national level when in early March 2003 Federal/Provincial/Territorial government representatives as well as other experts in the field of food surveillance for chemicals were invited to come together to a workshop to assess the current situation in Canada, and to develop recommendations for the establishment of a more efficient and effective coordinated system.

As well, in response to the announcement by the Swedish Food Authority of the detection of acrylamide in foods, scientists developed and validated an analytical method for acrylamide in food and were the first to discover how acrylamide is formed in certain foods. These research outcomes are essential to developing solutions to the problem.

Pre-market Evaluation

As one of our ongoing priorities and achievements, the Food Directorate evaluates submissions from industry before they are approved for market sale in order to minimize health and safety risks. Below is a short summary of our 2002-03 work in the area of pre-market evaluations:

- We completed approximately 380 food additive submissions (mainly food advisory opinions) this year. As well, there were approximately 1,500 general inquiries on food additives, flavours and processing aids, and approximately 660 requests associated with food contaminants.
- In the area of food packaging materials and incidental additives, we completed the review of over 2,000 submissions on food packaging and food contact materials and over 950 submissions respecting incidental additives such as cleaners and sanitizers.
- In microbiology we received, completed and/or addressed 12 submissions which dealt with processing aids to control microbial loads on meat, alternate container evaluation program, use of food colourants, adequate thermal processing, the safety of preservation processes, and chemicals that may come into contact with food or food contact surfaces.
- In the Food Directorate, 14 novel food submissions were received and decisions were taken on 11 submissions.

Health Risk Assessments and Food Recalls

In addition to evaluation of submissions from industry, the Food Directorate also conducts health risk assessments (HRA's) and safety evaluations of microbial hazards, chemical contaminants, food allergens and natural toxicants in foods.

HRA's indicate the likelihood of occurrence of foodborne illness, and assistance is also provided to the requesting agency regarding appropriate measures to reduce the risk associated with suspect food.

HRA's are conducted on an ongoing basis in response to requests primarily from the Canadian Food Inspection Agency. Requests do also come from provinces, other federal departments (e.g., Agriculture and Agri-Food Canada, Department of Fisheries and Oceans, and Department of National Defence) and other food industry organizations.

- In 2002-03, thirty-seven (37) Health Risk Assessments (HRA) and eighteen (18) requests for advisory opinions (RAO) were completed on fresh and preserved meat, vegetables, dairy products, sweets, poultry and seafood products. All of the these HRA's and requests for advisory opinions were CFIA requests and focussed around issues such as container integrity problems, inadequate thermal processing, the safety of preservation processes, the presence of non-pathogenic microorganisms and the potential presence of pathogens.
- We also conducted approximately 15-16 Health Risk Assessments for some key chemical contaminants, including acrylamide; morpholine (in apple coatings); heavy metals, focusing on mercury in fish; dioxins, furans, and dioxin-like PCBs.

Annex - Food Directorate Project Areas

The Food Directorate has identified and prioritized 27 Project areas which assist us in organizing our work.

<u>Rank</u>	Project Area
1.	Nutrition Labelling and Nutrient Content Claims
2.	Highest Risk Food Pathogens
3.	Novel Foods (Genetically Modified foods and other Novel Foods)
4.	Nutritional Quality / Safety of Foods (Includes Infant Formula and Foods providing Sole Sources of Nutrients)
5.	Food Allergens
6.	Food and Nutrition Surveillance
7.	Organic Chemical Contaminants (Includes Halogenated and Non-Halogenated Hydrocarbons)
8.	Prions (TSE's)
9.	Human Pathogenic Food Borne Parasites And Viruses
10.	Food Irradiation
11.	Dietary Reference Intakes
12.	Seafood Toxins and Biotoxins in Foods from Aquatic Environments
13.	Mycotoxins
14.	Antimicrobial Resistance and Use in Agriculture and Aquaculture
15.	Functional Foods and Health Claims
16.	Other High-Risk Food Borne Bacterial Pathogens (Includes Clostridium botulinum)
17.	Trace Toxic Elements
18.	Food Additives
19.	Suspected and Emerging Pathogens
20.	Herbs and Botanicals
21.	Food Packaging Materials (Includes Incidental Additives)
22.	Agricultural Chemicals
23.	Veterinary Drug Residue
24.	Probiotics: Industrial Applications of Microbial Cultures
25.	Low Risk Pathogens
26.	Microbial Indicators
27.	Extraneous Materials in Foods