



Health Products and Food Branch 2004-05 Performance Report

Highlights

Our mission is to help the people of Canada
maintain and improve their health.

Health Canada

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Assistant Deputy Minister's Message

I am happy to report on a year of progress and achievement for Health Canada's Health Products and Food Branch (HPFB) in 2004-2005. During this period, we continued to help Canadians to maintain and improve their health through enabling access to safe and effective products and reliable information to support informed choice and healthy decisions.

HPFB's work spans the life cycle of tens of thousands of health and food products, from clinical trials to surveillance, compliance and enforcement. Every day, we address complex regulatory, scientific, public policy, public health and risk communications issues on behalf of Canadians. In 2004-05, we spent approximately \$184 million to support our priorities in regulation, monitoring and surveillance, authoritative information, public and stakeholder involvement, and building a strong organization.

In 2004-05, we pursued a wide range of special initiatives aimed at strengthening our efficiency, effectiveness and responsiveness as a regulator. Indeed, our continued implementation of the Therapeutics Access Strategy (TAS), has already resulted in substantial improvements in the timeliness of our review process. For example, we were successful in reducing the backlog for new pharmaceutical drug submissions by 89%. By September 30, 2005, the backlog of pharmaceutical submissions was virtually eliminated and the proportion of regulatory decisions made within performance targets (for 2005 to date) had more than doubled to 58% compared to 25% in 2004.

In addition, we evaluated over 3,000 submissions related to food additives, packaging materials, novel and processed foods. We also initiated 40 new policy, standard-setting and research projects on food safety and continued to work closely with the Canadian Food Inspection Agency (CFIA) to assess the effectiveness of the Agency's food inspection programs.

As part of our ongoing efforts to provide authoritative information to help Canadians make healthy choices and informed decisions, we began the revision of *Canada's Food Guide to Healthy Eating* to ensure that it promotes a pattern of eating that meets nutrient needs, promotes health, minimizes the risk of nutrition-related chronic disease, and is more relevant and understandable to Canadians.

During the past year, we also expanded collaboration with key stakeholders across Canada. Such collaboration was critical to the development of a framework that provides Canadians with access to safe, effective and high quality natural health products. Working closely with our federal/provincial/territorial partners, we also implemented new measures to strengthen the capacity of Canada's food safety system to protect Canadian consumers, while supporting an innovative and sustainable food sector.

We introduced new mechanisms such as the Public Involvement Framework for informing and engaging Canadians. In addition, we consulted consumers, patients, academics, health professionals, industry, non-governmental organizations and government partners on such wide-ranging issues as cells, tissues and organs, food fortification, *Canada's Food Guide to Healthy Eating*, maximum residue limits for veterinary drugs, and the online publishing of Summary Basis of Decisions outlining the rationale and scientific basis of our regulatory decisions.

As we celebrate these and the many other achievements outlined in this report, we recognize that the way forward poses significant challenges. New ideas, innovations and scientific discoveries continue to transform Canadians' physical environments, health and health choices. Diseases – such as avian flu and BSE – have the potential to threaten our health and well-being. Such developments place enormous pressure on our regulatory system and scientific capacity to keep pace.

Our accomplishments in 2004-05 are part and parcel of our efforts to meet these ongoing challenges. Thanks to Health Products and Food Branch's dedicated staff, I have great confidence in our future as we help Canadians to maintain and improve their health.

Hélène Goulet
A/Assistant Deputy Minister
Health Products and Food Branch

Our Mandate

The Health Products and Food Branch takes an integrated approach to the management of the risks and benefits to health related to health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Who We Are

As Canada's authority for regulating health products and foods, the Health Products and Food Branch (HPFB) is an important contributor to Health Canada's work to help Canadians maintain and improve their health.

We evaluate and monitor...

- the safety, quality and efficacy of human and veterinary drugs, vaccines, medical devices, natural health products and other therapeutic products available to Canadians; and
- the safety and quality of foods Canadians eat, including those derived from animals treated with veterinary drugs.

We promote...

- the health and well-being of Canadians through the development of evidence-based guidelines, policies and standards.

How We Work

We strive to deliver our programs in a timely, efficient and cost-effective manner, utilizing ...

- sound science and effective risk management;
- a strong national approach supported by offices in every region of the country;
- strong partnerships with other governments, health care providers, non-governmental organizations, industry, academia; and
- international cooperative relationships to share information, collaborate on regulatory standards and processes, minimize duplication and leverage efforts.

For information about how we are organized, see Appendix 1.

What We Set Out to Do

Five strategic priorities in the 2004-07 HPFB Strategic Plan guided our program activities in regulating, monitoring, and informing Canadians about the safety of food and health products, and ensuring we remain accountable to Canadians.

Some of the highlights provided in this 2004-05 performance report are accounted for in one strategy for the purposes of accountability, clarity and brevity.

However, the results may be horizontal in nature and support other strategies.

This report should be read with this in mind.

<i>Priority</i>	<i>Activity</i>	<i>Key Results</i>
<p>Regulation</p> <p>Transforming our efficiency, effectiveness and responsiveness as a regulator.</p>	<p>We conduct pre-market regulatory evaluation of health products and food, with a focus on benefit/risk assessment and making process improvements to improve efficiency, effectiveness and responsiveness, while maintaining Health Canada's high safety standards.</p>	<p>Transformed regulatory processes.</p> <p>A regulatory platform for the 21st century.</p> <p>Expanded collaboration with international regulatory authorities.</p> <p>Leveraged national partnerships.</p> <p>Enhanced health innovation.</p>

<i>Priority</i>	<i>Activity</i>	<i>Key Results</i>
<p>Monitoring and Surveillance</p> <p>Increasing responsiveness to public health issues and greater vigilance of safety and therapeutic effectiveness in real world use.</p>	<p>We collect information on adverse reactions to health products, provide health risk assessments, identify and alert Canadians to health and safety risks and ensure health products meet Canadian and international standards.</p>	<p>Improved risk management and communications as a shared responsibility with stakeholders.</p> <p>Improved assessments based on research and surveillance.</p> <p>Enhanced post-market surveillance of safety and therapeutic effectiveness.</p> <p>Effective compliance and enforcement.</p> <p>Integrated role in health system.</p>
<p>Authoritative Information</p> <p>Providing authoritative information for healthy choices and informed decisions by Canadians.</p>	<p>We provide useful, reliable and timely information about the risks and benefits of health products, food and nutrition.</p>	<p>Useful and credible evidence-based information.</p> <p>Improved public awareness and healthy choices.</p> <p>Supportive conditions to enable Canadians to make informed and healthy choices.</p> <p>Strategic and coordinated communications.</p>

<i>Priority</i>	<i>Activity</i>	<i>Key Results</i>
<p>Public and Stakeholder Involvement</p> <p>Improving transparency, openness and accountability to strengthen public trust and stakeholder relationships.</p>	<p>We are improving accountability to Canadians through enhanced stakeholder and public involvement in our work and through improved and increased public reporting of results.</p>	<p>Increased public accountability.</p> <p>Enhanced transparency.</p> <p>Improved openness.</p>
<p>A Strong Organization</p> <p>Building a nationally-based organization with the capacity and flexibility to fulfill its mandate in an ever-changing environment.</p>	<p>We are investing in our workforce and strengthening the quality assurance and management tools, systems and processes that are vital to our continuing stability and effectiveness as an organization.</p>	<p>Strengthened nationally-based capacity for sustainable performance.</p> <p>Improved management tools and systems.</p> <p>Strategic management of corporate commitments and obligations.</p> <p>Leveraged technology to support a high-performing organization.</p> <p>Strengthened responses to emergencies.</p>

Regulation - What We Accomplished

Canadians demand timely access to safe and effective health products and food. This year, we again conducted thousands of pre-market evaluations of new products, while developing and implementing a wide range of new regulations, standards and process improvements.

Key Performance Indicators

- Pre-market submissions reviewed within performance targets.
- Modernized legislative tools, policies and regulatory approaches developed and implemented.

Themes

Activities and Selected Results

Stronger Review Practices

We continued to re-engineer pre-market review processes, applying the latest management tools to boost our capacity to meet established performance targets.¹ As a result:

... for health products

We reduced the review backlog for new pharmaceutical drug submissions by 89% and for biologic drug submissions by 7%.² We also reviewed 25% of new pharmaceutical drug submissions within established time targets, a 100% increase over last year.

We reviewed 67% of high risk and 81% of lower risk medical device applications within performance targets, significant improvements over last year.

We assessed 99% of Special Access Requests (for the provision of pre-market drugs and medical devices for treating patients with serious or life-threatening conditions) within performance targets.

As part of E-Review³, we rolled out an electronic review tracking system and began testing a new records and document information management system.

We launched a new scientific Laboratory Information Management System that will allow for better monitoring and tracking of biologics and genetic therapies that may present high risks to Canadians.

¹ With support from funding such as the Therapeutics Access Strategy, a five-year \$190 million investment to improve regulatory processes for human drugs and therapeutic products.

² Between April 1, 2003 and March 31, 2005.

³ E-Review is a multi-year initiative that seeks to establish a fully automated electronic system that supports the submission and review of drugs and therapeutic products.

Themes

Activities and Selected Results

... for food

We evaluated over 3,000 submissions related to food additives, packaging materials, novel and processed foods.

The review of some 13 submissions for novel foods (e.g., genetically-modified animals and plants) was completed.

... for veterinary products

We reviewed over 90% of veterinary drug submissions over 18 months old.⁴

We migrated 15,000 records to a new veterinary emergency drug release system.

New Regulations and Standards

We continued to ensure that policy, regulation and research support the responsible and timely introduction of new discoveries. For example:

...for food safety and nutrition

We introduced new policies and regulations regarding the chemical and microbiological safety, and nutritional value of Canada's food supply.

We analyzed stakeholder comments on revised safety assessments guidelines for novel foods and responded to recommendations made by expert committees on food biotechnology.

We continued to work closely with the Canadian Food Inspection Agency (CFIA) to support the implementation of new nutrition labelling regulations, and to provide advice on the labelling of food allergens and the potential risks associated with undeclared allergens.

To support the development of informed strategies for reducing the amount of trans fatty acids in food, we gathered expert input on fat reformulation strategies and viable, healthful alternatives.

We completed consumer testing of vitamin and mineral additions to foods, informing the development of regulatory amendments on food fortification.⁵

... for natural health products (NHPs)

We implemented a new regulatory framework⁶ for natural health products.

⁴ As of April 2004.

⁵ Proposed regulatory amendments are scheduled to be published in early 2006.

⁶ New regulations were introduced in January 2004 and are being implemented with the help of a \$10 million investment.

Themes

Activities and Selected Results

...for drug products

We made progress on development of a regulatory framework to support new legislation for the provision of low-cost medicines to developing countries suffering from deadly infectious diseases such as HIV/AIDS.

... for blood and tissue and organs

We updated national standards for cells, tissues and organs, furthered the development of a national regulatory framework and began compliance inspections.

We released guidance on the prevention of West Nile Virus and SARS transmission through transplantation.

International Cooperation⁷

To keep pace with global public health trends and rapid advances in science and technology, we continued to forge stronger links with international health and regulatory partners. For example:

... multilaterally

We streamlined submission requirements and implemented industry guidance for submissions in the International Conference on Harmonization (ICH) Common Technical Document (CTD) format. By co-Chairing the ICH Global Cooperation Group, we helped promote a better understanding and use of ICH guidelines, encouraged dialogue around good harmonization practices and enhanced the capacity of other nations' drug regulatory programs.

We continued participation with the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH). This enables Canada to have guidelines for data registration requirements for new veterinary medicinal products consistent with other countries.

We also hosted a World Health Organization conference on Cells, Tissues and Organs and co-chaired a SARS Vaccine Session at BIO 2004.

⁷ Making good use of resources and knowledge from other agencies and governments not only contributes to more informed, consistent and timely decisions, but also leads to common standards and practices, promotes technological innovation, and supports greater access for Canadians to the latest therapeutic products and methods.

Themes

Activities and Selected Results

... bilaterally

In cooperation with the **United States** Food and Drug Administration (USFDA), we agreed to establish a framework for cooperation on pharmaceutical quality issues, initiated discussions on third party quality systems audits for manufacturers of medical devices and co-sponsored a workshop on dating blood platelets.

In cooperation with **Australia's** Therapeutic Goods Administration we furthered work on the mutual exchange of information on drug review and regulatory practices, signed an agreement recognizing each others' pharmaceutical good manufacturing process assessments and began work on another agreement regarding quality systems certificates for medical devices. We also signed an agreement with Food Standards **Australia and New Zealand** to work cooperatively on such areas of mutual interest as the evaluation of novel foods, quantitative microbial risk assessments, and health claims for food and food fortification.

We initiated bilateral discussions with the National Institute for Biological Standards and Control (NIBSC) in the **United Kingdom**.

Monitoring and Surveillance - What We Accomplished

Canadians rely on us to monitor and alert them to the safety and health issues related to the more than 22,000 human drug products, 40,000 medical devices, and thousands of food products on the Canadian market. Again this year, we completed risk assessments of the safety, quality and effectiveness of hundreds of pharmaceutical drugs, biologics and medical devices, issuing product recalls, and advisories to health professionals and Canadians where appropriate.

Key Performance Indicators

- More and better tools available to all partners responsible for risk management and risk communications capacity in the regulatory system.
- Use of therapeutic effectiveness evidence to support formulary listing decisions for health products.
- Significant number of MedEffect portal users with increases over time.
- Increased number of adverse drug reactions reported to the new regional centres.
- Compliance of industry stakeholders with departmental regulations and standards.

Themes

Activities and Selected Results

Better Adverse Drug Reaction Protection

We enhanced our capacity to monitor and report on unintended reactions to prescription, non-prescription, biological and herbal drugs approved for the Canadian market. For example:

We added two new regional centres (Manitoba, Alberta) for reporting on adverse drug reactions.

... *monitoring*

We completed initial work on MedEffectCanada, a new system that gathers and provides information to the health care community on adverse reactions, medication problems and safe product use.

We continued to examine new mechanisms for identifying adverse drug reactions in children. This included undertaking a two-year study⁸ to determine the feasibility of active surveillance that will help inform the new HPFB Office of Paediatric Initiatives and the possible establishment of dedicated surveillance staff in children's hospitals across Canada.

⁸ In partnership with the Canadian Paediatric Society and the Women's Health Centre of British Columbia.

... reporting

To support more timely reporting of adverse reaction information, we provided specifications for the development of a handheld wireless tool for medical professionals which will be tested in 2005-06.

The number of new subscribers to our Health Products Information system increased by 18% to reach 10,000 subscribers.

We issued 50% more health product advisories, including 60 advisories for health professionals and 55 for the general public.

... compliance

Three new therapeutic product inspection programs were implemented to ensure industry compliance with existing and new regulations.

We carried out inspections of 24 (of a targeted 50) establishments to find almost 100% compliance with adverse drug reaction reporting requirements.

We also inspected 45 (of a targeted 70) medical device establishments and five (of a total of 120) cells, tissues and organs establishments. Inspections of medical device establishments fell short of targets as manufacturers developed appropriate responses to new reporting requirements.

Ensuring Food Safety and Nutrition

Under the Agricultural Policy Framework, we began 40 new policy, standard-setting and research projects aimed at enhancing on-farm food safety. In addition, we began work on an integrated national system on food safety.

We continued to work closely with the Canadian Food Inspection Agency (CFIA) to assess the effectiveness of the Agency's food inspection programs including those for poultry, fish and dairy. The Agency also provided feedback to inform our work to develop and refine food safety and nutritional quality standards and policies.

We continued to work with stakeholders to enhance the content and functionality of the Canadian Nutrient File.⁹

We invested \$500,000 to study the amount of nutrients and contaminants such as lead, mercury and other chemicals in Canada's food supply.

Working with Statistics Canada and other partners, we developed the nutrition component of the Canadian Community Health Survey (CCHS) cycle 2.2, Nutrition focus.

Stronger Protection against Emerging Risks

We remained vigilant in identifying and developing timely and effective responses to emerging issues related to food, nutrition and health products. For example:

⁹ The Canadian Nutrient File is the standard database used by Health Canada and non-governmental organizations for reporting the amount of nutrients in foods commonly consumed in Canada.

- ... mad cow disease** We invested \$2 million on BSE-related research on the risks of eating Canadian-produced beef and beef products.
- ... look alike/sound alike drugs** We continued to closely monitor and look for new ways to minimize the risks that “look-alike/sound-alike” drugs may pose in terms of prescribing, dispensing or administration errors. We also published pre- and post-market guidelines. However, we encountered privacy concerns that delayed plans for Canada-U.S. agreement to facilitate information sharing and electronic monitoring of these products.
- ... genetically modified foods** We continued to conduct research into the development of health surveillance methodologies and techniques for the detection of genetically-modified fish.
- ... novel foods** We continued to contribute to different stages of policy development and evaluation of novel foods, including studying the allergy potential of novel foods.
- ... food contaminants** Following reports of high levels of chemical fire retardants in farmed fish, we conducted further research on the toxicological effects on humans and concluded that the levels found do not pose an unacceptable health risk.
- We are developing new methodologies to determine concentrations of various emerging marine and fresh-water toxins.
- We conducted national surveys of foods for various contaminants, including veterinary drug residues and pesticides.
- We continued to set maximum residue limits for veterinary drugs in foods derived from animals and established five additional limits.

Authoritative Information - What We Accomplished

Canadians had better access to the information they needed to make informed decisions about their health and well-being because of our work to provide the latest reliable, evidence-based information about food, nutrition and health products. Again this year, we reached out to Canadians through a wide range of publishing, advertising, public outreach and marketing efforts.

Key Performance Indicators

- Increased awareness and knowledge among consumers and patients of health products, food and nutrition issues.
- Informed choices made by consumers and patients demonstrating more safe and healthy behaviours relating to health products, food and nutrition.

Themes	Activities and Selected Results
New Information	We continued to provide current, reliable and easy-to-understand information to Canadians on a wide range of topics. For example:
<i>... on adverse drug reactions</i>	We distributed the <i>Canadian Adverse Reaction Newsletter</i> to over 99,000 physicians, pharmacists and other subscribers across Canada and around the world. We also assessed information available on the effectiveness and safety of health products including those affecting children.
<i>... on biotechnology</i>	We provided information on the regulatory system for food, health, environment, drugs and health products made by biotechnology. We engaged stakeholders through trade events on biotechnology. As well, we continued the development of a new website.
<i>... on natural health products</i>	We invested \$50,000 as part of a multi-year \$500,000 initiative to develop research networks and consulted with the Canadian Institutes of Health Research (CIHR) and the Institute of Aboriginal People's Health (IAPH) as part of an effort to establish research partnerships on natural health products.

Themes

Activities and Selected Results

... drugs

We continued working on policy development and implementation plans to make product monographs accessible to the public.
We distributed fact sheets on new topics such as the safe disposal of pharmaceutical products.

Promoting Food Safety and Nutrition

We continued to promote the *Fight BAC!* campaign which seeks to educate consumers about safer food handling procedures and strengthened efforts to reach out to “high risk” consumers.

We began the revision of *Canada’s Food Guide to Healthy Eating* to ensure that it promotes a pattern of eating that meets nutrient needs, promotes health, minimizes the risk of nutrition-related chronic disease, and is more relevant and understandable to Canadians. In addition, we conducted research on how to make the Food Guide more applicable and appealing to Canadians.

We continued to disseminate a variety of healthy eating resources, including *Canada’s Food Guide to Healthy Eating*. The *Canada’s Food Guide to Healthy Eating* webpage registered a 15% increase in visits and was the most visited page on Health Canada’s website.

We published two new infant feeding recommendations and disseminated approximately 40,000 copies to health professionals.

We also distributed resources to assist consumers to better understand the new nutrition labels on pre-packaged food products, including approximately 300,000 copies of the Nutrition Labelling tearsheet for consumers and over 30,000 Nutrition Labelling posters, with distinct resources for First Nations and Inuit. A series of articles was produced for distribution to the public through News Canada.

Public and Stakeholder Involvement - What We Accomplished

Canadians and our stakeholders including consumers, patients, academics, health professionals and industry were more involved in health products, food and nutrition policy, decision making and program development because of our efforts to better inform, engage and consult them about our ongoing work. These activities provided HPFB with new perspectives and knowledge that are reflected in modified regulations, guidance documents, directives, policies and approaches. The importance of these initiatives is reflected in the statistic that 80% of Canadians say they would have a more positive view of government decisions that are based on public input.

Key Performance Indicators

- Improved public and stakeholder opinion about the Branch's accountability for results and the timeliness and transparency of its regulatory process.
- Sustained public confidence and trust in health products, food and the regulatory system.
- Increased stakeholder awareness of the Branch's business and decision-making processes.
- More individuals accessing information online.
- Increased public involvement in Branch program and policy development, implementation and decision-making.

Themes

Activities and Selected Results

Responding to Canadians

We responded to nearly 2,600 requests for information within a one-day timeframe, a 55% increase in the number of requests handled last year.

We also began work to establish a new Office of the Public Ombudsman to handle complaints, concerns and feedback from individuals and organizations about our work.

Themes

Activities and Selected Results

Engaging Canadians

We continued to seek new ways to give Canadians and health stakeholders the opportunity to have their say on important health product and food safety issues, while ensuring timely regulatory decisions and progress. For example:

We held 34 meetings with 17 advisory committees that were established to provide advice and feedback on such issues as neuropathic pain, breast implants, and reprocessing of medical devices.

We held workshops with 134 participants in 11 cities across Canada as part of the process of developing a new Public Involvement Framework.

We also undertook over 100 separate activities to consult on topics such as the Public Involvement Framework, cells, tissues and organs, food fortification, *Canada's Food Guide to Healthy Eating*, maximum residue limits for veterinary drugs, and the online publishing of Summary Basis of Decisions outlining the rationale and scientific basis of our regulatory decisions.

Patients and consumers across Canada took part in a pilot information and training session on HPFB decision-making processes concerning the review of drugs for safety purposes before they are authorized for sale in Canada.

We also hosted a national stakeholder forum to share information and solicit input on key initiatives, such as the federal government's Smart Regulations Initiative, and legislative renewal for food safety and nutritional quality policy.

A Strong Organization - What We Accomplished

Maintaining our capacity to manage highly intricate regulatory, scientific, public policy, public health, communications and legal considerations is critical to our success in serving Canadians. To effectively manage corporate risks and gather the scientific evidence we need to act in the public interest, we continue to improve our management tools, systems and processes across all program areas. Recognizing that nearly one-quarter of our scientific staff are eligible for retirement before 2007-08, we are also taking important steps to sustain our scientific knowledge base and the critical workforce strength we need to meet our regulatory obligations.

Key Performance Indicators

- Sustainable and flexible workforce.
- Improved science capacity.
- Reduced number of workplace health and safety incidents.
- Use of resource tracking systems linked to performance.
- Meeting immediate and ongoing information management and technology needs.
- Implemented emergency preparedness plans and guidelines.

Themes

Activities and Selected Results

Stronger Emergency Response

To ensure our capacity to protect essential operations and maintain services to Canadians during emergencies, we developed and tested business continuity plans.

We contributed to an Emergency Preparedness Partnership Framework between Health Canada and the Canadian Food Inspection Agency.

We developed a Food-borne Illness and Outbreak Response Protocol to ensure clear roles, responsibilities and coordination of food-borne illness outbreaks by federal, provincial and territorial food and public health agencies.

**Ensuring
Objective Internal
Review**

We created a branch audit and evaluation office along with a supporting governance structure.

**Managing Our
People**

We continued progress on developing employee succession, staffing, orientation, training and development plans to ensure our employees have the skills, remuneration, training and other support required to be productive.

**Planning and
Performance**

We released an upgraded version of the Program Management and Reporting System that complements the existing departmental financial system.

We continued to refine our management framework, including approaches to recovering revenues, planning, budgeting and reporting.

**Managing our
Technologies and
Information**

We continued to consolidate all information technology functions, including creating common database applications, and consolidating IT equipment and infrastructure.

We continued to implement initiatives regarding identification of essential records, retention and disposition programs.

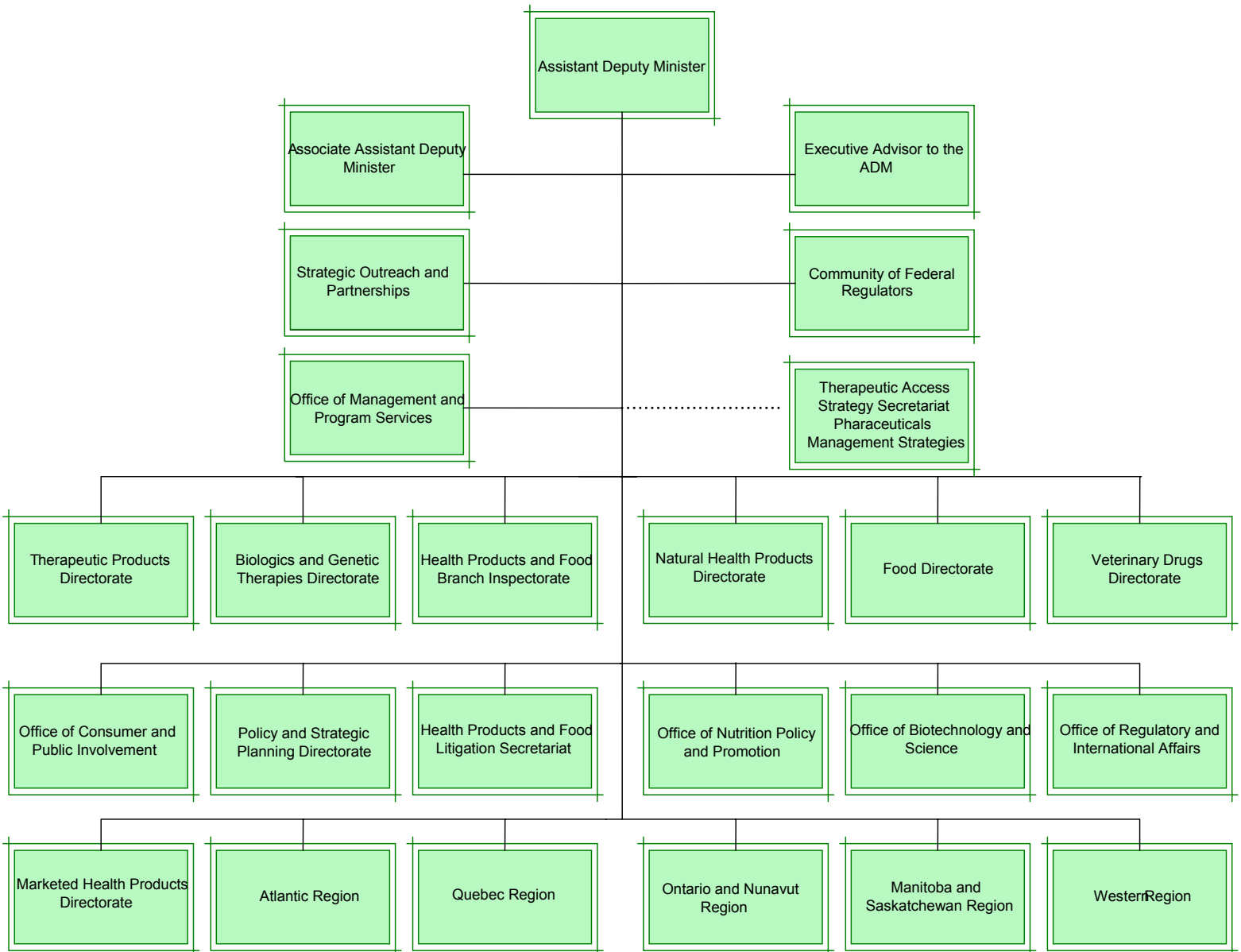
We have invested in new technologies such as E-review, and using the Internet to improve communications with our stakeholders and Canadians generally.

We took advantage of technological advances to support information sharing. Through CANLINE, for example, we enabled federal, provincial and territorial stakeholders to share inform and create a national repository of data on chemical contaminants in food. Through eLEXNET, we facilitated real-time sharing of laboratory information.

Appendix 1: How We Are Organized

This is an organizational overview of the Health Products and Food Branch (HPFB) and a brief description of the mandates and functions of each Directorate.

Health Products and Food Branch



Organization Unit	Mandate
Assistant Deputy Minister's Office (ADMO)	Advises the Minister, manages parliamentary relations, correspondence and briefing materials, and identifies and manages high visibility risk issues.
Biologics and Genetic Therapies Directorate (BGTD)	Regulatory authority for the safety, quality and efficacy of biological drugs and radiopharmaceuticals for human use (e.g., genetic therapies, blood and blood products, tissues, organs, etc.).
Food Directorate	Establishes policies and standards related to food safety and nutrition and assesses the effectiveness of the activities of the Canadian Food Inspection Agency (CFIA) related to food safety.
HPFB Inspectorate	National compliance and enforcement program of all products under the mandate of HPFB except food.
HPF Litigation Secretariat	Manages litigation and legal risks.
Marketed Health Products Directorate	Works to assure programs take a consistent approach to post-approval safety surveillance, assessment of signals and safety trends, and risk communications concerning all regulated marketed health products.
Natural Health Products Directorate	Ensures that all Canadians have ready access to natural health products and information.
Office of Consumer and Public Involvement	Provides Canadians with information and opportunities to become meaningfully involved in the decision-making process.
Office of Biotechnology and Science	Provides Departmental focal point for biotechnology, Branch focal point for science issues, and science library services to Health Canada and the Public Health Agency.
Office of Management and Program Services	Coordinates corporate services in areas such as human resources, workplace health, learning, training and education, finance, administration, information management and information technology.
Office of Nutrition Policy and Promotion	Collaboratively defines, promotes and implements evidence-based nutrition policies and standards.
Office of Regulatory and International Affairs	Improves HPFB's ability to deliver its domestic and international regulatory policy objectives by facilitating regulatory cooperation.
Policy and Strategic Planning Directorate	Leads the development of HPFB's policy agenda, strategic and business planning, and input into Health Canada planning initiatives.
Regional Offices	Contributes to the activities of all Directorates by conducting research, outreach and other activities across the country.
Therapeutic Products Directorate	Regulatory authority for the safety, efficacy and quality of pharmaceutical drugs and medical devices for human use.
Veterinary Drugs Directorate	Evaluates and monitors the safety, quality and effectiveness, sets standards and promotes the prudent use of veterinary drugs administered to food-producing and companion animals.

Appendix 2: Links to Additional Information

Throughout this report are many initiatives for which additional information is available online. The following key links are provided for the reader's convenience.

HPFB homepage

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index_e.html

TAS Progress Report

http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2005-therap-strateg/index_e.html

Canada's Food Guide to Healthy Eating

http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index_e.html

Food Fortification

http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/index_e.html

Nutrition Labelling

http://www.hc-sc.gc.ca/fn-an/label-etiquet/index_e.html

Food Allergens

http://www.hc-sc.gc.ca/fn-an/securit/allerg/index_e.html

Trans Fats

http://www.hc-sc.gc.ca/food-aliment/e_trans_fat.html

Natural Health Products

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/index_e.html

Canadian Adverse Drug Reaction Newsletter

http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/index_e.html

MedEffect

http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html

Public Involvement Framework

http://www.hc-sc.gc.ca/ahc-asc/pubs/cons-pub/piframework-cadrepp_e.html

Fact sheets

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/3kit-fiche/index_e.html

Summary Basis of Decision

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/proj/sbd-smd/index_e.html

Selective COX-2 inhibitor NSAIDs - Expert Advisory Panel meeting and public forum

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-consult/cox2/forum_index_e.html

Review Performance Report

http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/performance_rendement_2004_e.html