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Health Products and Food Branch

2007–08 Business Plan

Our key priorities and activities

Canada

Health Products and Food Branch

2007–08 Business Plan

Our key priorities and activities

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Message from the Assistant Deputy Minister

Meena Ballantyne
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

I am pleased to present the Health Products and Food Branch's *2007–08 Business Plan*, which outlines our key priorities and activities for this fiscal year. It is a key tool to help us plan, measure, and report our performance and demonstrates the Branch's commitment to promote and protect the health and safety of Canadians.

Since its creation in 2000, Health Canada's Health Products and Food Branch (HPFB) has been working to meet new and increasingly complex challenges to help Canadians maintain and improve their health. Our work spans the life cycle of tens of thousands of health and food products. Everyday, we must

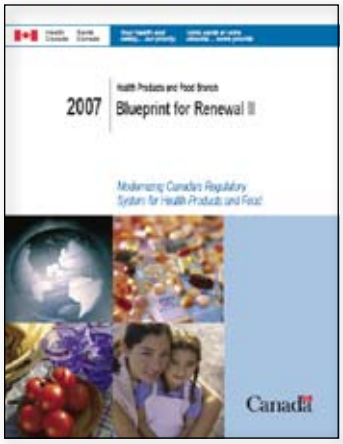
- ensure continued and timely access by Canadians to safe and effective health products and a safe and nutritious food supply;
- evaluate and monitor the safety, quality, and effectiveness of human and veterinary drugs, vaccines, medical devices, and other therapeutic products available to Canadians, as well as the safety and quality of the foods we eat;
- continue to be a trusted source of authoritative information; and
- work to promote conditions that enable Canadians to make healthy choices and informed decisions related to health products, food, and nutrition.

While we continue to be respected internationally as a modern regulator, the complexity and challenges of our work continue to expand as new ideas, innovations, and scientific discoveries drive growth in biologics, genetic therapies, vaccines, and food products. To anticipate and meet these challenges, we need to modernize our regulatory system.

"To improve the trust and confidence that Canadians have in the Branch's work and in the regulatory system, we are committed to improving our operational planning process."

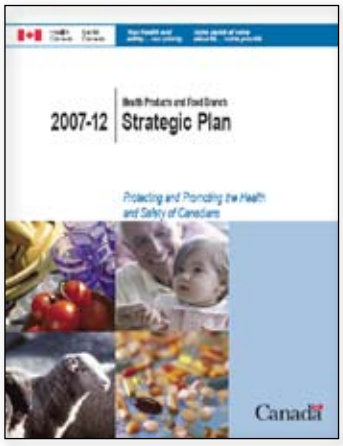
Blueprint for Renewal II

Our *Blueprint for Renewal II* is available at www.healthcanada.gc.ca/hpfb-blueprint.



2007–12 Strategic Plan

Our *2007–12 Strategic Plan* is available at www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index_e.html.



In October 2006, we released our *Blueprint for Renewal*, to take a comprehensive review of our approach to regulating health products and food. The comments received from the consultations on the Blueprint were critical to developing the *HPFB 2007–12 Strategic Plan* and the updated *Blueprint for Renewal II*. Our *2007–08 Business Plan* identifies concrete steps we will take to implement our commitments in both documents.

As a science-based organization, excellence in science is the cornerstone of our credibility and our ability to accomplish our mission. Consequently, we are developing, for the first time, a strategic science plan for 2007–12. Our Business Plan identifies the initiatives we are undertaking to fulfill this commitment.

To improve the trust and confidence that Canadians have in the Branch's work and in the regulatory system, we are committed to improving our operational planning process, as recommended by the Auditor General of Canada. This Business Plan links our Strategic Plan with our internal operational plan for 2007–08, and we intend to prepare a yearly Business Plan that provides comprehensive information on our activities.

The HPFB team is composed of dedicated and professional individuals. Their ongoing contribution, in collaboration with our stakeholders, will enable us to foster innovation and strengthen HPFB's regulatory capacity. As we move forward, I know that HPFB will continue to play a vital role in protecting the health and safety of Canadians, and I look forward to the successful implementation of this *2007–08 Business Plan*.

About the Health Products and Food Branch

Who we are

Health products include human and veterinary drugs, vaccines, blood and blood products, natural health products, pharmaceuticals, radiopharmaceuticals, biologics and genetic therapies, medical devices, and other therapeutic products.

As Health Canada's federal authority responsible for regulating **health products** and food through the *Food and Drugs Act*, the Health Products and Food Branch (HPFB) evaluates and monitors the safety, quality, and effectiveness of the thousands of human and veterinary drugs, vaccines, medical devices, natural health products, and other therapeutic products available to Canadians, as well as the safety and quality of the foods they eat.

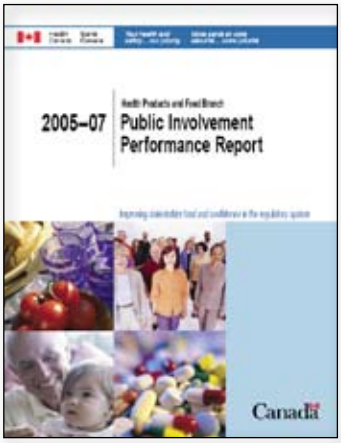
The Branch's responsibilities include ensuring that veterinary drugs sold in Canada are safe and effective for animals and that the foods derived from animals treated with those drugs are safe. HPFB also promotes the health and well-being of Canadians through a broad range of activities related to health products and food, including developing nutrition policies and standards such as *Canada's Food Guide*.

HPFB strives to ensure that the potential benefits of all health products outweigh their risks. Our highest priority is public safety. Before any health product or veterinary drug is authorized for sale in Canada, the manufacturer must provide HPFB with substantive scientific evidence of its safety, efficacy, and quality. Highly skilled HPFB scientists review this evidence carefully to determine whether the potential risks from the health product are acceptable when balanced against its positive effects. HPFB takes a similar approach to food. HPFB also establishes policies, sets standards, and provides advice and information on the safety and nutritional value of food.

High safety and quality standards also apply to health products that have reached the Canadian market. HPFB

- monitors all health products available for sale in Canada for compliance with manufacturing, advertising, and labelling regulations and guidelines;
- monitors expected and unexpected health risks such as adverse reactions to drugs;
- enforces the *Food and Drugs Act* and associated regulations, when necessary; and
- assesses the effectiveness of the activities of the Canadian Food Inspection Agency that are related to food safety.

2005–07 Public Involvement Report
The report provides an overview of the public involvement activities completed by HPFB in 2005–07, and is available at http://www.hc-sc.gc.ca/ahc-asc/pubs/cons-pub/pub-invol-perf-rap_rap-rend-part-pub-tc-tm_e.html.



HPFB is committed to being transparent, open, and accountable to Canadians. Performance targets, safety measures, and results are documented in its *2007–12 Strategic Plan* and annual performance report. A variety of public involvement activities offer Canadians opportunities to contribute to regulatory decisions about the health products they use and the food they consume every day.

In all its activities, from regulatory affairs to policy development, from compliance monitoring to engaging other governments at home and abroad, Health Canada is committed to promoting and protecting the health and safety of all Canadians. Through regulations and consistent, high standards, HPFB supports Health Canada's goal to provide Canadians with timely access to safe, effective, and high-quality health products and food, and the information they need to maintain and improve their health.

How we work

Vision

To play a vital role in protecting and promoting the health and safety of all Canadians by excelling as a trusted scientific and regulatory authority for health products and food in Canada and internationally.

Mission

We help Canadians maintain and improve their health by:

Evaluating and monitoring

- the safety, quality, and efficacy of the health products they use;
- the safety and quality of the foods they eat; and
- the safety, quality, and effectiveness of veterinary drugs to protect the safety of Canada's food supply.

Developing, promoting, and implementing nutrition and food policies and standards.

Providing timely, evidence-based, and authoritative information to allow healthy and informed decisions.

Anticipating and responding to public health and safety issues associated with health products, food, and nutrition.

Values

We have five core values that define how we carry out our day-to-day work and the results we want to achieve.

Independent, evidence-based decisions

We make sound, evidence-based decisions using a multidisciplinary approach, anchored in science. We are recognized, nationally and internationally, for our scientific research and expertise, and our evidence-based decisions in collaboration with authoritative experts.

Openness and transparency

We foster open communication in our organization and with our health partners, stakeholders, and the public. We provide timely, complete, and accurate professional responses to enquiries. We ensure transparency in our decision making and information sharing.

Cooperation

We cooperate with other levels of government, other departments, experts, the public, and stakeholders to develop policies and programs that meet their evolving needs. We develop strategic international partnerships to increase our effectiveness and results for Canadians.

We uphold Health Canada's three core values

- Caring for the people of Canada
- Taking pride in what we do
- Building a workplace community

Effective management

We strive for excellence in management by ensuring that our structure, processes, plans, and organization are continually aligned with our strategic directions. We engage in sound financial and people management practices by

- ensuring that our structure and processes are aligned with the priorities and objectives of the Government of Canada;
- building and sustaining a strong workforce through effective recruitment, development of employee competencies, continuous learning and innovation, and fostering a stimulating work environment; and
- delivering our programs in a timely, efficient, and cost-effective manner, using public and cost recovery funds responsibly to ensure value and benefits for Canadians.

Accountability

We ensure that our work serves the interests of Canadians, and that we are accountable for our results through government and public scrutiny. We maintain our regulatory independence from external stakeholders while valuing their perspectives.

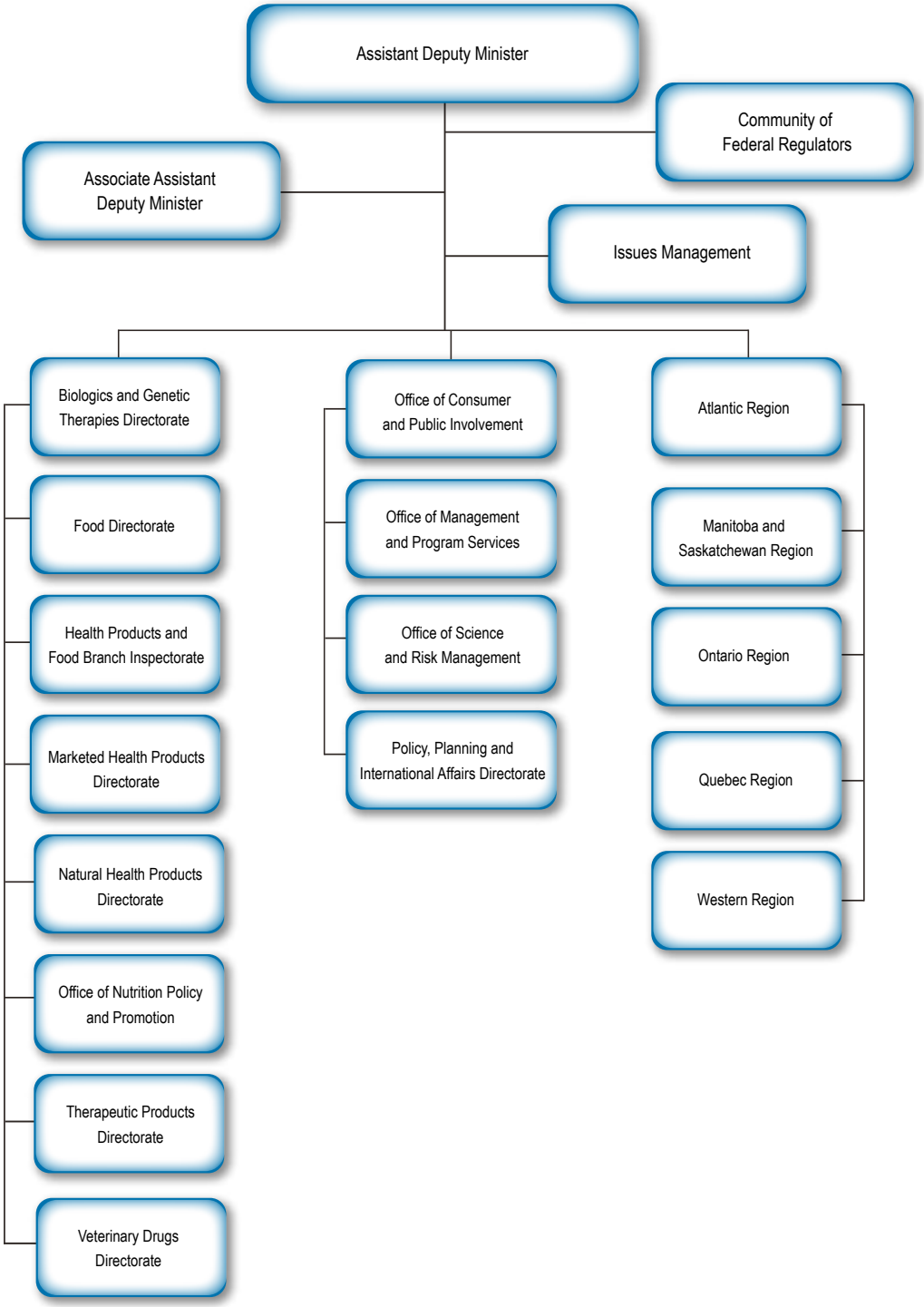
Strategic objectives

Our *2007–12 Strategic Plan* outlines the six strategies that will guide us forward, address our increasingly complex challenges and help us continue to deliver concrete results for Canadians over the next five years.

How we are organized

Organizational structure

Health Products and Food Branch, Health Canada



Mandates

Organization	Mandate
Assistant Deputy Minister's Office	Advises Minister; manages parliamentary relations, correspondence and briefing materials; and identifies and manages corporate risk issues.
Biologics and Genetic Therapies Directorate	Regulates the safety, quality and efficacy of biologics and biotechnology products, such as vaccines; blood and blood products; cells, tissues, and organs; gene therapies and biotherapeutics.
Community of Federal Regulators	Builds and sustains the capacity of the federal regulatory community through learning, partnerships and best practices.
Food Directorate	Establishes policies and standards for food safety and nutrition and assesses the effectiveness of the activities of the Canadian Food Inspection Agency for food safety.
Health Products and Food Branch Inspectorate	Manages a national compliance and enforcement program for all products under the mandate of the Branch, except food.
Marketed Health Products Directorate	Coordinates post-market surveillance and assessment of signals and safety trends.
Natural Health Products Directorate	Ensures that Canadians have timely access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.
Office of Consumer and Public Involvement	Provides Canadians with information about health products and food and about opportunities to become meaningfully involved in the regulatory decision-making process.
Office of Management and Program Services	Implements corporate services in areas such as human resources; workplace health; learning, training and education; finances; 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 Science and Risk Management	Provides a focus for coordination and development of science within the Branch, as well as advice on international, federal, and departmental science and technology issues affecting the Branch.
Policy, Planning and International Affairs Directorate	Provides a centre of excellence in planning, policy and regulation; Cabinet, parliamentary, federal-provincial-territorial, and international affairs; and audit and evaluation.
Therapeutic Products Directorate	Regulates pharmaceutical drugs and medical devices for human use.

Organization	Mandate
Veterinary Drugs Directorate	Protects human and animal health and the safety of Canada's food supply by evaluating and monitoring safety, quality, and effectiveness; setting standards; and promoting the prudent use of veterinary drugs administered to food-producing and companion animals.
Regional Offices	Contribute to the activities of all Directorates by conducting research, outreach and other activities.

Our people

In conducting our activities, we face a host of complex regulatory, scientific, public policy, public health, communications, and legal issues. Our success in managing these challenges depends on building and maintaining a strong, national organization with the capacity and flexibility to fulfill its mandate.

HPFB is a science-based branch that is part of a larger science and technology (S&T) community, including 10 other science-based federal departments. Our focus on science distinguishes us from other parts of the federal public service in many ways—our career paths, aspirations, and plans for retirement, for example, are closely aligned with those of the greater S&T community. It is within this science-based context that we must plan for our future.

Did you know?

- The percentage of S&T employees in Health Canada: 36%
- The percentage of HPFB employees in S&T: 60%
- The percentage of S&T employees in Health Canada that work in HPFB: 40%

Our unique characteristic as a science-based organization as well as anticipated changes in our workforce and technology means we need, now more than ever, effective human resources and operational planning. Securing our future will require the Branch to ensure that

- staffing plans identify staffing priorities and fill identified gaps;
- the career plans and aspirations of HPFB employees are well understood by their managers and are communicated in a manner that enables the Branch to assess trends and address anticipated gaps;
- knowledge and skills capacities are sustained and expanded;
- learning activities reflect individual and organizational objectives;
- human resource planning is integrated with our operational priorities;
- we maintain and build our capacity to deliver on our activities to help Canadians maintain and improve their health; and
- we attract and maintain a competent, flexible, and dedicated staff who contribute to the success of the organization.

Achieving our strategic priorities

To realize our vision, the Health Products and Food Branch's *Blueprint for Renewal II* identifies **10 key policy objectives** to modernize the regulatory system for health products and food.

These 10 policy objectives are directly linked to the six strategies in our *2007–12 Strategic Plan*. Each strategy outlines key strategic actions and key results.

10 key policy objectives

1. A product life cycle approach in regulating health products that will encompass all stages of product development and use
2. A more efficient and transparent system of categorizing products and assessing their risks
3. Strengthened compliance and enforcement
4. A modernized regulatory approach for food safety and nutrition
5. A proactive and enabling regulatory system that engages stakeholders and helps influence the future
6. A stronger post-market surveillance system
7. An emphasis on specific populations (for example, children and seniors) for a range of health and safety issues
8. Increased transparency and openness to involve, for example, patients, consumers, health professionals, and researchers
9. More and better information about health products and food
10. An integrated system by synchronizing better with the objectives, policies, and practices of the health care and innovation system

- Blueprint for Renewal II

1 Strategy 1: Adopt a life cycle approach to regulating health problems

Key result

- The Branch's safety oversight is strengthened through continuous evaluation of the safety, quality, and effectiveness of health products before and after they reach the Canadian market.

2 Strategy 2: Promote health through a modernized food regulatory system and a proactive approach to nutrition

Key results

- The Branch's oversight of food safety and nutritional quality is strengthened.
- Canadians are better informed and able to manage their health by making healthier food choices.
- Canadians' social and physical environments support healthy eating.

3 Strategy 3: Advance international cooperation and be an international leader

Key result

- The Branch's capacity and performance is improved through international cooperation.

4 Strategy 4: Establish strategic partnerships to fulfill our mandate

Key result

- The Branch's effectiveness is enhanced through national partnerships.

5 Strategy 5: Better integrate transparency, openness, and accountability into our day-to-day work

Key results

- Canadians have improved access to timely and authoritative information to make healthy and informed decisions.
- Canadians have improved trust and confidence in the Branch's work and in the regulatory system.

6 Strategy 6: Build a nationally based flexible organization that can fulfill its mandate and priorities in a changing environment

Key results

- The Branch's infrastructure and facilities meet evolving program needs.
- The Branch's technology supports a high-performing organization.
- The Branch has a highly skilled, adaptable, and motivated workforce.
- The Branch's responses to emergencies are strengthened.

Our 2007–08 Key Priorities and Activities

This section outlines Branch priorities and activities for 2007–08, along with timelines for each strategy. We will measure and report the results of our work through key performance indicators.

1 Adopt a lifecycle approach to regulating health products

The Branch will begin to implement a regulatory approach that recognizes that health products have a life cycle that encompasses all stages of product development and use, both before and after the product reaches the market. We will also continue to strengthen our post-market activities and risk assessment capabilities while carrying out establishment inspections and compliance verifications of marketed products.

KEY PRIORITY: Safety oversight of health products

The Branch will strengthen our authorities and tools to effectively monitor the safety, effectiveness, and quality of health products before, during, and after their introduction to the Canadian market. At the same time, we will continue to meet our performance target for submission reviews of health products and work to reduce the submission backlog for veterinary drugs and natural health products. In 2007–08, we will work on the following:

Key activities	Timelines	Key performance indicators
New regulatory frameworks for health products		
Develop and implement new regulatory frameworks for		
• blood and blood components intended for transfusion;	Spring 2008	Percentage of blood and blood component initiatives completed on schedule
• human cells, tissues, and organs for transplantation; and	Published in *Canada Gazette II* early 2007	Percentage of cell, tissue and organ initiatives completed on schedule
• vaccines and radiopharmaceuticals.	Spring 2008	Percentage of vaccine and radiopharmaceutical initiatives completed on schedule
Develop a new regulatory framework (Progressive Licensing) for pharmaceuticals and biologics, which will allow us to monitor, assess, and communicate information about drugs throughout the product life cycle.	Spring 2008	Percentage of progressive licensing framework initiatives completed on schedule

Key activities	Timelines	Key performance indicators
Develop proposals for regulatory and non-regulatory aspects for the implementation of a Progressive Licensing Framework.	2008	Percentage of progressive licensing framework initiatives completed on schedule
Review of regulatory frameworks for health products		
Continue work on the comprehensive review of the Special Access Program (SAP), which provides Canadians with limited access to drugs and medical devices that cannot otherwise be sold or distributed in Canada. This work will include • launching stakeholder consultations for comprehensive review of the SAP; and • pre-publishing in *Canada Gazette I* the regulatory amendment to permit block release of non-marketed drugs to address public health emergencies.	External consultations to identify the major issues and concerns for the SAP, spring 2007 Web-posting of the issue identification paper to ensure a common understanding of SAP issues, fall 2007 Public Forum to obtain feedback from all interested Canadians on the proposed options for modernizing the SAP, spring 2008	Percentage of SAP initiatives completed on schedule
Continue work on the review of the regulatory framework for clinical trials, which was launched in 2006, to ensure that the framework is flexible, robust, and able to respond to pressures and trends.	Post report on stakeholder workshop, June 2007 Release the action plan for a series of Health Canada phased initiatives to further support strengthening the protection of human research participants, and attracting and sustaining investments in research and development, December 2007	Percentage of clinical trials regulatory framework initiatives completed on schedule
Regulatory interventions proportional to risk		
Enhance product classification capacity so that the regulatory requirements and interventions within and between regulatory frameworks are proportional to risk and applied in a more consistent and timely manner.	Draft guidance document on products at the drug-cosmetic interface for public consultation, June 2007 Final guidance document posted, winter 2008	Percentage of product classification capacity initiatives completed as planned

Key activities	Timelines	Key performance indicators
Continue the review of the *Natural Health Products Regulations*, launched in 2006, to address issues related to natural health products that cross into other regulatory frameworks and product categories such as drugs or food.	Consultations on issues: spring 2007; consultations on proposed options: fall 2007	Percentage of the NHP regulations review initiative completed
Compliance and enforcement		
Strengthen the effectiveness of compliance and enforcement programs		
• expand and strengthen the Medical Device Inspection Program;	193 medical device inspections, by March 2008	Number of inspections
• expand and strengthen the Clinical Trials Inspection Program;	86 clinical trial inspections, by March 2008	
• advance the key components of Blueprint II that fall within the responsibility of the Branch's Inspectorate, namely the Compliance Strategy, which focuses on new legislative authorities, an analysis of risk, performance measures, and partnership building; and	New compliance and enforcement authorities under the *Food and Drugs Act* by December 2007	
• develop and deliver the Anti-Counterfeit Strategy. The strategy outlines compliance and enforcement mechanisms to increase the Inspectorate's capacity to detect and identify counterfeit health products, reduce the opportunity for counterfeit health products to enter the Canadian supply chain, and increase consumer awareness of the risks associated with counterfeit health products.	Develop Strategy and implementation plan, October 2007 Conference between Royal Canadian Mounted Police, Health Canada, Canadian Border Services Agency, fall 2007	Extent to which the Anti-Counterfeit Strategy is developed and delivered Number and type of tools and regulations developed to address counterfeit-related risks
Keeping pace with technological and scientific advances and evolving needs of stakeholders and Canadians		
Establish a foresight program and develop or adapt guidance from regulatory or harmonization bodies (for example, the International Conference on Harmonisation) to outline regulatory requirements for new technologies and clinical research processes (for example, radiopharmaceuticals).	Ongoing	Extent to which the foresight program on new technologies and clinical research processes is developed

Key activities	Timelines	Key performance indicators
Continue to work with other departments and stakeholders to ensure that new products and procedures derived from biotechnologies, nanotechnologies, and other health-related emerging technologies have been adequately evaluated for their safety to humans, animals, and the environment.	Ongoing	Number of policies, regulations, standards, and guidelines developed and approved
Continue to provide scientific and regulatory advice on research and development relating to the safety, effectiveness, and quality of health products. This helps address challenges in the product development process by • providing better safety data on new and innovative drug products; • considering post-authorization, pharmacovigilance (post-market surveillance) and risk management planning earlier to improve the quality of product submissions; and • generating greater health benefits from investments in research.	Ongoing	Extent to which initiatives to address product development process challenges are completed
Post-market surveillance and monitoring		
Strengthen post-market activities, including the surveillance and monitoring of safety and therapeutic effectiveness. We will • implement the Canada Vigilance System, which will focus initially on post-market adverse reactions to pharmaceuticals, biologics, and natural health products, and later be expanded to include pre-market adverse reaction reports from clinical trials;	Targeted for March 31, 2008	Percentage of post-market activities completed on schedule

Key activities	Timelines	Key performance indicators
• develop a Pharmacovigilance Toolkit to strengthen our post-market surveillance capacity. The toolkit will allow easy access to guidance documents, information management, and prioritization strategies, as well as additional information sources such as Periodic Safety Update Reports and the analysis of foreign adverse reaction data;	Targeted for full launch by March 2008	Extent to which the Pharmacovigilance Toolkit is developed
• increase emphasis on pediatric needs as a pilot for other at-risk populations;	Developmental work on key issues throughout 2007–08	
• develop a Branch approach to post-market labelling changes; and	Ongoing	
• establish an expert advisory committee on health product vigilance.	November 2007	
Emphasis on specific populations		
Continue meeting the specific needs of children through the recent establishment of the Office of Paediatric Initiatives, by establishing a Paediatric Expert Advisory Committee to provide advice on regulatory and related issues regarding health products used by children.	Ongoing	Extent to which the Paediatric Expert Advisory Committee is established
Regulatory review of performance for all health products		
Continue to review, within internationally comparable time target, 90 per cent of submissions for pharmaceuticals and biologics.	Ongoing	Percentage of decisions made within performance target by type of health product submission
Meet or exceed our performance target for the review of medical devices 90 per cent of the time.	Ongoing	

Key activities	Timelines	Key performance indicators
Establish and meet 90 per cent of decisions made within the performance target for natural health products.	Ongoing	Percentage of decisions made within performance target by type of health product submission
Establish and meet performance targets for veterinary drug submissions in the areas of submission screening, experimental studies certificates, drug identification numbers, and emergency drug releases.	Ongoing	Percentage of pre-market product submissions backlog reduced
As a part of the Therapeutic Safety Initiative, increase the number of clinical trial inspections.	In 2007–08, conduct 85 clinical trial inspections, which meets the international benchmark of 2 per cent of all clinical trials inspected annually	

2 Promote health through a modernized food regulatory system and a proactive approach to nutrition

Canada has a strong food safety system. However, the current regulatory system needs to adapt to changes in the organization, scale, and orientation of the food market, as well as to changes in the amount and type of food science information that is available to Canadians. It needs to respond to Canadians who want to be more engaged in shaping the regulatory requirements for the food supply. In addition, the system must continue to provide timely, accessible, and accurate information on healthy eating and the nutritional value of food in order to foster informed and healthy choices.

The work conducted by the Branch contributes to the following outcomes:

- A safe and nutritious Canadian food supply
- Information to support healthful food choices to help Canadians maintain good health and prevent chronic and acute food-related illness and disease

KEY PRIORITY: Oversight for food safety and nutritional quality

The Branch will continue to ensure that our regulatory system for food and nutrition is able to respond to new challenges and that regulatory standards continue to be influential and positive contributors to improved health for all Canadians. The Branch will also modernize its policies and practices to respond to safety issues and challenges related to food and nutritional quality. In 2007–08, we will do the following:

Key activities	Timelines	Key performance indicators
Pre-market review process improvement for food and veterinary drugs with a focus on transparency, predictability, and responsiveness		
To modernize the Food Directorate's submission review processes, we will		
• develop a backlog reduction strategy;	By March 31, 2008	Percentage of pre-market product submissions backlog reduced, by type of submission
• conduct outreach activities to industry to improve the quality of submission packages and/or develop an electronic toolkit to complement guidelines. We will explore education tools to assist petitioners in the preparation of submissions guidelines;	By March 31, 2008	Number of information products related to food and nutrition disseminated to industry and/or Canadians

Key activities	Timelines	Key performance indicators
• develop a standard operating procedure for determining what constitutes a novel food to guide regulatory decision making in the Food Directorate; and • develop a tiered assessment approach for novel foods based on the risk posed by these products.	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
Implement regulatory frameworks that maximize the safety and nutritional quality of the Canadian food supply and promote food innovation and informed choices		
In developing a regulatory framework for health claims, we will • pre-publish in *Canada Gazette I* regulatory amendments for new health claims for use in Canada; and • release a consultation paper on the framework for health claims.	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
In developing a Food Fortification regulation, we will • publish in *Canada Gazette I* regulatory proposals to implement the revised policy on adding vitamin and mineral nutrients to foods, work on publication in *Canada Gazette II*, and prepare guidance and training materials.	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
In developing a Food Irradiation regulation, we will • finalize a Government of Canada position on extending the uses of Food Irradiation.	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted

Key activities	Timelines	Key performance indicators
In developing an allergen regulation and related activities, we will • publish in *Canada Gazette I* proposed regulatory amendments on an enhanced declaration of priority allergenic ingredients in pre-packaged foods; and • update the compliance policy to manage food allergen cross-contamination incidents.	Complete surveillance activities in support of risk assessment, March 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
Modernize the approach for managing food additives	In 2007–08, develop a consultation document on options for food additives regulatory renewal	Extent to which the consultation document on options for food additives is completed
In order to release and consult on a food regulatory modernization strategy, we will • continue work on the Regulatory Modernization Strategy for Food and Nutrition, including the release and consultation on *Towards a Regulatory Modernization Strategy for Food and Nutrition – A Health Canada Public Consultation Document.*	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
Regarding the release of the trans fat task force report and preparation of a government response, we will • finalize the government position on the strategy to reduce trans fats in the Canadian food supply, and • monitor the trans fat content of foods sold in popular fast food restaurants and in targeted foods (for example, bakery products, margarine, etc.) and release results.	By March 31, 2008 Ongoing	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted Number of information products related to food and nutrition disseminated to the industry and/or the Canadian public

Key activities	Timelines	Key performance indicators
To increase consumer awareness of ways to avoid the risks associated with unpasteurized juices, meats, raw milk cheese, and sprouts, we will develop a communication plan with the Canadian Food Inspection Agency (CFIA) to address concerns about produce.	By March 31, 2008, publish in *Canada Gazette I* a regulation that would require safe handling and cooking messages on all raw ground meats In 2007–08, continue the education campaign for meat and poultry (for example, a Web page on poultry safety) By March 31, 2008, publish results of the public consultation on mandatory labelling of unpasteurized fruit juice and cider In 2007–08, develop strategy options for raw milk cheese In 2007–08, develop communication plan and appropriate educational tools for sprouted beans and seeds	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted Number of information products related to food and nutrition disseminated to the industry and/or the Canadian public
Implement the food-borne contaminants initiative of the government's Chemical Management Plan		
We will contribute to the government's Chemical Management Plan (CMP) (and update risk management strategies to limit exposure of Canadians to selected chemicals in foods) by • developing an integrated Food Chemical Surveillance plan (through Health Canada's Food Chemical Safety Network); • assessing results of the canned tuna survey and developing subsequent risk management measures (including revised consumption guidance);	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted

Key activities	Timelines	Key performance indicators
• developing a communication plan on the risks of mercury in fish and the benefits of fish consumption; • conducting various food surveillance activities related to the CMP — specialty fish survey, perchlorate in bovine milk, dioxins/furan in free range eggs, PCBs/dioxins/PBDEs in commercial samples from Great Lake fisheries; • assessing high priority chemicals as part of the Challenge program (for example, exposure to Bisphenol A from food sources); and • Publish the first Total Diet Study report as a Health Canada publication.	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
Develop and implement a strategy to address emerging threats to food safety		
In working toward the Security and Prosperity Partnership, we will • amend the Canadian Good Agriculture Practices document	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted
Develop and implement a strategy for a healthier and safe food supply, in partnership with Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency, including long-term monitoring of the food-to-health pathway		
To strengthen Agriculture–Health collaboration and pursue Next Generation Agriculture Policy (NGAP) opportunities, the Food Directorate will • represent the Branch in discussions with Agriculture and Agri-Food Canada, the CFIA, and the provinces/territories in providing strategic input and advice into the development of NGAP options and priorities.	By March 31, 2008, obtain support from ADMs from health and agriculture departments (federal, provincial, and territorial) to consolidate tri-level food safety and inspection committees into one new food safety committee	Number of meetings with food safety partners on matters of joint interest; opinions and advice provided to industry, provinces and territories, etc.; and health risk assessments provided to the Canadian Food Inspection Agency

Key activities	Timelines	Key performance indicators
We will enhance relationships with industry and conduct other general outreach activities. We will enhance relationships with the Canadian Food Inspection Agency, federal-provincial-territorial partners, and the Public Health Agency of Canada.	By March 31, 2008, complete an annual report on food safety activities of federal-provincial-territorial governments	Number of meetings with food safety partners on matters of joint interest; opinions and advice provided to industry, provinces and territories, etc.; and health risk assessments provided to the Canadian Food Inspection Agency
Information for healthy eating		
We will make available translated and multilingual versions of the Web application My Food Guide that can be printed from the Health Canada Web site. The 11 translated languages: Arabic, Chinese (traditional and simplified), Korean, Persian, Punjabi, Russian, Spanish, Tagalog, Tamil, and Urdu. We will continue to enhance efforts to increase consumers' understanding and awareness of the information available on food labels to assist them in making informed choices by • integrating nutrition labelling messaging into key nutrition publications and communications initiatives.	By mid-August 2007	Number of information products on food and nutrition disseminated to industry and/or Canadians
We will share insights of results from the Canadian Community Health Survey - Nutrition with stakeholders and Canadians to help build capacity and inform nutrition-related initiatives.	Release of *Income-Related Household Food Security in Canada* (June 8, 2007) Release of *Nutrient Intakes from Food: Summary Data Tables, Volume 1* (September 21, 2007) By March 31, 2008, prepare and post a series of fact sheets on what Canadians are eating	Number of information products on food and nutrition disseminated to industry and/or Canadians

Key activities	Timelines	Key performance indicators
	In 2007–08, launch Canada's Nutrition and Health Atlas (CNHA) Web-based tool for reporting on nutrition related indicators	Number of information products on food and nutrition disseminated to industry and/or Canadians
We will update key recommendations from Health Canada's national pregnancy guidelines, *Nutrition for a Healthy Pregnancy.*	By March 31, 2008	Policies, regulations, standards, reports, plans, assessments, or guidelines developed and approved, and associated surveillance/ research activities conducted

3 Advance international cooperation and be an international leader

The Branch will continue to seek opportunities to incorporate international best practices into our regulatory system and harmonize with other nations or international organizations such as the World Health Organization, the International Conference on Harmonisation, and Codex Alimentarius. The Branch will be better able to protect the health and safety of Canadians by building and maintaining these relationships.

KEY PRIORITY: A focused approach to international cooperation

The Branch will expand and improve international collaboration and cooperation to advance Canada's health and safety priorities, while maintaining global harmonization. In 2007–08, we will work on the following:

Key activities	Timelines	Key performance indicators
Moving to an integrated system		
Develop and implement a strategy for working with international partners on a bilateral and multilateral basis, including the implementation of the Branch's strategic approach to International Regulatory Cooperation (worksharing/ harmonization). We will • continue to implement the HPFB International Regulatory Cooperation (IRC) Strategic Framework; and • advance work and information sharing that further domestic regulatory performance.	Ongoing	Number and type of standards, guidance, and information exchanged
Build and enhance strategic networks to advance international cooperation and scientific collaboration. This includes working closely with our international regulatory partners on issues of mutual interest. For example, • under the HPFB-FDA Memorandum of Understanding, we will hold a Strategic Policy Forum to map out policy directions related to medical devices; and	By March 31, 2008	Time taken to assess, plan, and implement recognized international guidance and standards

Key activities	Timelines	Key performance indicators
• through the Security and Prosperity Partnership, Canada, the United States, and Mexico will collaborate on human and avian influenza pandemic planning.	Ongoing	Time taken to assess, plan, and implement recognized international guidance and standards

4 Establish strategic partnerships to fulfill our mandate

The Branch will continue to fulfill its responsibilities through partnership with other stakeholders who share the common responsibility to help ensure the health and safety of Canadians. These include the provinces and territories, health researchers, health care providers, industry, and individual Canadians.

KEY PRIORITY: Stronger national partnerships

The Branch will continue to strengthen its relations with domestic partners, including provincial and territorial governments, industry, consumer and advocacy groups, and academia. In 2007–08, we will work on the following:

Key activities	Timelines	Key performance indicators
Stronger post-market system		
Establish partnerships to improve collection, assessment, and dissemination of safety and effectiveness information for health products, food, and nutrition, including a federal-provincial-territorial national network of centres of clinical evaluation excellence.	Throughout 2007–08	Number and type of harmonized initiatives adopted
Domestic scientific partnerships		
Develop and implement a 2007–12 Strategic Science Plan to advance our science priorities and build science capacity. We will use the plan to strengthen our scientific partnerships in Canada, including with the Canadian Institutes of Health Research.	Throughout 2007–08	Number and type of harmonized initiatives adopted

Key activities	Timelines	Key performance indicators
Federal-provincial-territorial partnerships		
Continue to strengthen cooperation with federal-provincial-territorial governments and non-government organizations in the health system. We will • co-chair the Nova Scotia Food and Health Products Safety Network with the Nova Scotia Department of Agriculture and Fisheries. The Network is composed of experts in food, water, health products, and animal health issues who work together to improve the efficiency and effectiveness of the regulatory systems.	Release proactive and preventive strategies and post-incident reviews of significant investigations, in 2007–08	Number and type of harmonized initiatives adopted

5 Better integrate transparency, openness, and accountability into our day-to-day work

The Branch will continue to build stronger relationships with a more diverse range of stakeholders to promote a more open and transparent regulatory system. Specifically, we will strengthen and increase the involvement of stakeholders, including patients, consumers, health professionals, and researchers in the Branch's decision-making process.

KEY PRIORITY: Increased transparency and openness

The Branch will enhance the quality of its decision making through increased transparency, openness, and accountability. In 2007–08, we will work on the following:

Key activities	Timelines	Key performance indicators
New legislative and policy tools		
Implementation of the *Review of Regulated Products: Policy on Public Input* and related guidance. The suite of tools will provide direction to HPFB and stakeholders on the specific circumstances in which the Branch may seek public input to improve the quality of the decisions we make and improve outcomes for Canadians.	Seek authorities and develop a governance framework, performance measures, awareness support, and training activities in 2007–08	Number and nature of new tools and approaches implemented to improve access to timely and authoritative information to make healthy and informed decisions
Stakeholder involvement		
Involvement of stakeholders and the public early, consistently, and at appropriate points in our decision-making processes. Integration of stakeholder input in new and more collaborative ways.	Release a performance report on Branch public involvement activities in 2008	Percentage of public and stakeholders involved in issues related to health products, food, and nutrition

Key activities	Timelines	Key performance indicators
Enhancing transparency of clinical trials		
Implementation of an approach for the registration and disclosure of clinical trial information that is consistent with international practices. This approach will allow for improved public access to relevant, accurate, and meaningful clinical trial information while respecting the need for academic and commercial confidentiality, as well as privacy.	Implementation of approach targeted to begin in the summer of 2007	Extent to which the approach for the harmonization with international practices for registration and disclosure of clinical trial information activities is implemented
More and better information about health products and food and nutrition		
Development and implementation of strategies to provide Canadians with timely and accessible information they can trust on health products and food and nutrition to make healthy and informed decisions. We will		Number and nature of new tools and approaches implemented to improve access to timely and authoritative information to make healthy and informed decisions
• implement a Branch consumer information strategy and outreach strategy to effectively engage consumers and stakeholders in the day-to-day work of the Branch. We will identify new and effective ways to improve the way the Branch communicates information to consumers and improve the tools, practices, and partnerships for doing so;	Consultations with stakeholders throughout 2007–08 Improvements to HPFB consumer information throughout 2007–08	Number of information products related to health products, food, and nutrition disseminated
• continue to disseminate key nutrition guidance documents, such as the revised *Canada's Food Guide*;	Ongoing	
• increase consumers' awareness of risk avoidance practices for unpasteurized juices and raw meat; and	Ongoing	
• enhance effective and timely communications of health product safety information to Canadians. This will include a Risk Communication Strategy to enable effective and timely communication of safety information.	Consultations and guidance document for Web site: winter 2007–08	

Key activities	Timelines	Key performance indicators
Addressing health and safety affecting specific populations		
Strengthened leadership on a range of health and safety issues affecting specific populations for food, nutrition, and health products. We will		Extent to which emphasis on paediatric needs is increased
• continue to increase our emphasis on pediatric needs as a pilot for other at-risk populations through the implementation and sustainability of the Office of Pediatric Initiatives.	Ongoing	
Consultations with stakeholders and the public		
Ongoing consultations on the *Blueprint for Renewal II* and its various activities, including consultations on the Progressive Licensing Framework, the Cost Recovery Initiative, the Special Access Program, the Regulatory Modernization Strategy for Food and Nutrition, and the review of the *Natural Health Products Regulations*.	Ongoing	Percentage of *Blueprint for Renewal II* initiatives completed on schedule
Regular communications with stakeholders through HPFB's *Involving You* newsletter, as well as targeted mailouts and e-mails.	Quarterly publications throughout 2007–08	

6 Build a nationally-based, flexible organization that can fulfill its mandate and priorities in a changing environment

The Branch will take important steps to sustain our scientific knowledge base and the critical workforce strength required to meet our obligations. To effectively manage risks and gather the scientific evidence we need to act in the public interest, we will continue to improve our management tools, systems, and processes across all program areas.

KEY PRIORITY: Fulfilling our organizational mandate

The Branch will continue to recruit a talented workforce and invest in staff training and infrastructure to ensure that we have the right knowledge and tools to do our work. In 2007–08, we will do the following:

Key activities	Timelines	Key performance indicators
Integrated Branch human resources plan		
Develop and implement a Branch staffing strategy, including • developing and implementing a human resources plan; and • building and sustaining a highly skilled, adaptable, and motivated workforce through effective recruitment, development, and retention strategies.	Throughout 2007–08 Ongoing	Extent to which the workforce is sustainable and flexible
A sustainable, high-performance, science-based organization		
Build science capacity in the Branch through strategic science planning, performance assessment, information gathering, science communications, and reporting.	Ongoing	Extent to which the workforce is sustainable and flexible
Promote learning and development by encouraging a regulatory community-learning environment to build capacity.	Ongoing	Extent to which the workforce is sustainable and flexible
Conduct research and build tools to increase knowledge and enable the sharing of expertise and best practices.	Ongoing	Extent to which performance measurement, evaluation, and planning frameworks are strengthened and implemented

Key activities	Timelines	Key performance indicators
As part of the Comprehensive Review of Programs and Resources initiative, develop a business case to articulate new requirements to sustain and improve future regulatory activities. This includes continued investments in scientific capacity, laboratory infrastructure, information management, and information technology, as well as requirements related to the implementation of the *Blueprint for Renewal II*.	Fall 2007	Extent to which the Business Case is developed
Finalize the cost recovery framework and consult stakeholders on fee proposals for individual product lines.	By March 31, 2008	Extent to which the cost recovery framework and stakeholder consultations are completed
Strengthened Branch financial management		
In response to the Auditor General report regarding the funding of regulatory programs, continue work on the renewal of our resource requirements.	Implementation of the business case for the Comprehensive Review of Programs and updated cost recovery regime, in 2007–08	Percentage of Comprehensive Review initiatives completed on schedule
Information systems and management		
Design and develop an integrated Branch information strategy, involving the Branch-level Information Management Strategy, Natural Health Products Online Solution, E-review, Canada Vigilance Project, and E-Consultations.	Significant progress is targeted for March 31, 2008	Number and type of resource tracking systems linked to performance implemented
As part of the Branch Information Management Strategy, implement a new organizational structure for the Science Library Network, and develop and finalize its strategic plan.	Ongoing	Extent to which the Branch Information Management Strategy is implemented Number and type of resource tracking systems linked to performance implemented
Help enhance capacity for benefit/ risk decision making in the Branch by supporting and improving the operations of the Risk Management Information System.	Ongoing	Extent to which the workforce is sustainable and flexible

Key activities	Timelines	Key performance indicators
Increased administrative managerial transparency		
Develop and implement a communications strategy that emphasizes clear and transparent, inward and outward communication of policies and procedures.	Implementation by March 31, 2008	Extent to which the communications strategy is developed and implemented Number and type of resource tracking systems linked to performance implemented
Planning, performance, and evaluation frameworks		
Implement the new Branch Strategic Plan, the new Branch Program Activity Architecture, and Performance Measurement Framework.	Throughout 2007–08	Extent to which performance measurement, evaluation, and planning frameworks are strengthened and implemented
Conduct a summative evaluation for the Food Safety and Nutrition Quality, the Natural Health Products, and the Human Drugs programs.	Initiate in 2007–08 for completion in 2008–09	
Implement the evaluation of the Access to Medicines Regime.	Completion in 2007–08	

Conclusion

To achieve the best results for Canadians, we will ensure that we remain a world-class organization with long-term sustainability and flexibility to meet their evolving needs. We will continue to respond to changes in our legislative, regulatory, and policy responsibilities and improve our management practices and processes to ensure accountability, openness, and transparency and the effective use of resources. We will also update our planning, performance, evaluation, and reporting frameworks to help us enhance our decision making and way of doing business. The end result: meeting our commitment to promote and protect the safety of Canadians and contribute to Health Canada and the Government of Canada priorities.