Health Canada Santé Canada

# Health Products and Food Branch 2005-06 Business Plan

## Highlights

Canada

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 pleased to present the Health Products and Food Branch (HPFB) Business Plan for 2005-06. It highlights how we plan to build on our successes and find innovative ways to address the challenges we face as we help Canadians to maintain and improve their health.*

The Health Products and Food Branch plays a key role in helping Canadians to maintain and improve their health by enabling timely access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices. The Branch does this through minimizing health risks to Canadians and maximizing the safety provided by the regulatory system, promoting the conditions that enable Canadians to make healthy choices, and providing information so that they can make informed decisions. HPFB's work spans the life cycle of tens of thousands of health and food products, from clinical trials, reviews of product submissions, to surveillance, compliance and enforcement.

HPFB continues to make progress in delivering on its Strategic Plan (2004-07) in order to meet the needs of Canadians and the priorities of government as a more responsive, open and transparent organization fulfilling our important public health responsibilities. In 2005/06, we will continue to improve our regulatory performance for the review of drug and other health product submissions, while taking important new steps to provide more information to the public on health products, food and nutrition and to increase public input into regulatory decision-making.

Throughout this document, you will find highlights of planned activities for the 2005-06 fiscal year. Although by no means exhaustive, the highlighted activities in this business plan demonstrate our commitment to protecting and promoting the health and health choices of Candians.

Diane Gorman
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 structured, see Appendix 1.

## *Our Strategic Priorities*

*Five strategic priorities in the 2004-07 HPFB Strategic Plan continue to guide our 2005-06 program activities in regulating, monitoring, and informing Canadians about the safety of health products and food, ensuring we remain accountable while building and maintaining a strong organization.*

*For purposes of clarity and brevity, our highlighted plans are presented under only one of the strategic priorities. However, the activities may be horizontal in nature and support other strategies.*

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

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

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

# *Regulation – Highlighted Plans*

*Canadians demand timely access to safe and effective health products and food. In the year ahead, we will conduct 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 (KPIs)**

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

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Strengthening review practices and results** | HPFB will continue to strengthen the efficiency and effectiveness of its review processes for human and veterinary drugs submitted for authorization and release to the Canadian market. For example, we will: | |
| *...clear backlogs and meet performance targets* | • Meet or exceed our performance targets for the review of new pharmaceutical drug submissions 90% of the time. | **1** |
| | • Make substantial progress in clearing the backlog for biologics drug submissions, enabling us to meet performance targets in 2007. | **1** |
| | • Continue to improve submission review performance for veterinary drugs and natural health products. | **1** |
| *... new industry guidance* | • Develop a Good Guidance Practices Framework to enhance guidance to industry for improved quality and consistency of submissions. | **2** |
| *... modern systems and process* | • Introduce new processes and systems that allow for the receipt, processing and review of submissions in an electronic environment and improve overall project management. | **2** |

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Regulating health products** | HPFB will continue to enhance the safety of drugs, medical devices and other therapeutic products available to Canadians. For example, we will: | |
| *... new plasma regulations* | • Introduce new regulations to ensure donor and patient safety with respect to plasmapheresis (i.e., the process of extracting plasma from donated blood and returning remaining components to the donor). | **2** |
| *... new regulations for cells, tissues and organs* | • Introduce new national standards-based regulations for cells, tissues and organs. | **2** |
| *... new regulations for biotechnologies* | • Develop a new biotechnology stewardship framework to assure the responsible introduction of new discoveries. | **2** |
| **Food safety and nutrition** | HPFB will work with its partners[1] to assure the safety and nutritional quality of food for all Canadians. For example, we will: | |
| *... mandatory labelling* | • Ensure that all large manufacturers meet new mandatory labelling requirements of Nutrition Facts Table, by December 2005. | **2** |
| *... reducing trans-fats in foods* | • Continue working with a multi-stakeholder task force to develop recommendations for reducing trans-fats in Canadian foods to the lowest levels possible, while ensuring that alternatives are safe. | **2** |
| *... national coordination* | • Work with federal partners, provinces and territories to enhance national decision-making on food safety and nutrition issues. We will begin development of a strategy including public health outcomes that will demonstrate achievements to Canadians and international partners. | **2** |
| *... under the Agricultural Policy Framework* | • Continue work on policy and standard setting projects launched in 2004-05 under the Agricultural Policy Framework to effectively address public health hazards at the farm and industry level. | **2** |

[1] Federal partners include the Canada Food Inspection Agency (CFIA), Agriculture and Agri-food Canada and the Department of Fisheries and Oceans.

| Themes | Highlighted Plans | KPI |
|---|---|---|
| *... limiting veterinary drug residues in food* | • Further prohibit the personal importing of drugs intended for use in food-producing animals and continue to add to the regulatory list of safe residue limits for veterinary drugs in foods. | **2** |
| *... keeping pace with technological and scientific advances* | • Update policies and regulations to address issues of antimicrobial resistance[2] and the addition of vitamins and minerals to foods through policy and regulatory development. | **2** |
| | • Update how we conduct safety assessments of novel foods (e.g., genetically-modified animals and plants) to minimize risks to Canadians. | **2** |
| **International cooperation** | HPFB will strengthen links with international partners to ensure Canadians continue to be served by a world-class regulatory system that keeps pace with global public health trends and rapid advances in science and technology. For example, we will: | |
| *... with the U.S. and Mexico* | • Collaborate with the U.S. and Mexico in the areas of drugs, biologics, medical devices, food safety and nutrition.[3] We will lead the development of a performance management framework and take over leadership of working groups on laboratories and health fraud. | **2** |
| | • Participate in a food-related emergency exercise and co-host, with the Canadian Food Inspection Agency, the meeting of a tri-national task force charged with conducting the assessment and identification of food safety coordinating mechanisms.[4] | **2** |

[2] Antimicrobial resistance (AMR) occurs when a specific antimicrobial drug is ineffective in killing or slowing down the growth of a targeted microorganism. The emergence of AMR threatens our ability to fight human and animal diseases with potentially serious public health implications.
[3] This work falls under the provisions of a Trilateral Cooperation Charter between Canada, the U.S. and Mexico.
[4] This work falls under the provisions of the Security and Prosperity Partnership of North America (SPP).

| Themes | Highlighted Plans | KPI |
|---|---|---|
| *... with Australia* | • Continue to implement the agreement with Australia's Therapeutic Goods Administration (TGA), which provides for information-sharing on new technologies and methods, as well as safety, efficacy and quality standards. | **2** |
| | • Identify an appropriate biologics submission to conduct a parallel review between ourselves and the TGA. This pilot review project is one mechanism to share information on current review and decision-making practices. | **2** |
| | • Implement the work plan arising from a 2005 Memorandum of Understanding with the Australian Pesticide and Veterinary Medicines Authority to increase international cooperation and information-sharing. | **2** |
| *... with the U.K. and European partners* | • Contribute to the international consultation on the United Kingdom's National Institute for Biological Standards and Control's proposed reorganization. | **2** |
| *... for developing countries* | • Further the development of a regulatory framework to support new legislation for the provision of low-cost medicines to developing countries suffering from infectious diseases such as HIV/AIDS. | **2** |

# *Monitoring and Surveillance – Highlighted Plans*

*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, as well as thousands of food products on the Canadian market. In the year ahead, we will continue to strengthen our risk assessment capabilities, while carrying out establishment inspections and compliance verifications of marketed products.*

**Key Performance Indicators (KPIs)**

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

| **Themes** | **Highlighted Plans** | **KPI** |
|---|---|---|
| **Research** | HPFB will continue to work with its partners to conduct research activities to assess and report on the safety and benefits of health products and food available to Canadians. For example, we will: | |
| *... understanding emerging issues* | • Collaborate with and provide guidance to industry on requirements for the development and approval of a vaccine to address the risks of pandemic influenza. | **2** |
| | • Conduct Bovine Spongiform Encephalopathy (BSE)-related research and enhance risk assessments to human health of bovine-derived health products and food. | **1, 5** |
| *... on food contaminants and other safety issues* | • Invest in research and monitoring of chemical contaminants, microbial hazards and pathogens in Canada's food supply. | **1** |

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Surveillance** | HPFB will continue to collect, analyze and share information related to the safety, effectiveness, quality, risks and benefits of health products, food and nutrition. For example, we will: | |
| | • Build upon the Canadian Laboratory Information Network (CANLINE) to create a repository of data on levels of contaminants in foods consumed by Aboriginals. | **1** |
| | • Further the development of detection and analytical methodologies for Canadian Food Inspection Agency (CFIA) laboratories and conduct assessments of the effectiveness of CFIA's food safety activities and programs. | **1** |
| *... on nutrition* | • Broaden the use of the Canadian Nutrient File (CNF), the high-quality standard reference on nutrients in foods commonly consumed in Canada. | **1** |
| | • Develop and disseminate a user's guide to assist nutrition stakeholders in interpretation of the findings of the Canadian Community Health Survey (CCHS) 2.2, nutrition focus. | **1** |
| | • Develop a themed report on Household Food Security following the release of the CCHS 2.2 wave 1 data. | **1** |
| *... on adverse drug reactions* | • Continue work with health care professionals, consumers and patient groups on MedEffectCanada, a new system that gathers and provides information on adverse drug reactions (ADRs), medication problems and safe product use. | **3, 4** |
| | • Examine new mechanisms for identifying ADRs in children, including the completion of a two-year study[5] to determine the feasibility of active surveillance of ADRs in children and development of a publicly accessible information database on drug safety issues related to children. | **1, 2** |

[5] This study is in partnership with the Canadian Paediatric Society and the Women's Health Centre of British Columbia.

| Themes | Highlighted Plans | KPI |
|---|---|---|
| | • Expand our capacity to monitor and evaluate clinical trial ADRs and safety information.<br><br>• Begin testing a handheld wireless tool designed to support the timely reporting of adverse reaction information by health care professionals. | **2**<br><br>**1, 4** |
| **Risk Management**<br><br>*… on single-use medical devices* | HPFB will continue to strengthen its management of product safety-related risks in collaboration with stakeholders. For example, we will:<br><br>• Identify and implement options for minimizing the risks associated with single-use medical devices. | <br><br>**1, 2** |
| **Compliance and Enforcement** | HPFB will continue compliance and inspection activities to ensure that health products meet standards for safety, quality and efficacy. For example, we will:<br><br>• Carry out compliance inspections of establishments with respect to human drugs, veterinary drugs, natural health products, medical devices and blood, tissues, organs and xenografts.<br><br>• Continue the development and implementation of compliance mechanisms for cells, tissues and organs.<br><br>• Implement recommended changes to the medical devices program made by the Office of the Auditor General[6]. | <br><br>**5**<br><br>**5**<br><br>**1, 5** |

[6] 2004 Report of the Auditor General of Canada, Chapter 2 – Health Canada – Regulation of Medical Devices, March 2004.

# *Authoritative Information – Highlighted Plans*

*As new health products and food enter the marketplace, Canadians increasingly demand the latest reliable, evidence-based information. In the year ahead, we will continue to inform Canadians about healthy eating and help them to make healthy choices.*

**Key Performance Indicators (KPIs)**

1. Increased awareness and knowledge among consumers and patients of health products, food and nutrition issues.

2. Informed choices made by consumers and patients demonstrating more safe and healthy behaviours relating to health products, food and nutrition.

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **User-friendly information** | HPFB will continue to provide current, reliable and easy-to-understand information to Canadians on a wide range of topics related to health products, food and nutrition. For example, we will: | |
| *... on dietary guidance and nutrition labelling* | • Complete the revision of *Canada's Food Guide to Healthy Eating* to ensure it continues to promote a pattern of eating that meets nutrient needs, promotes health and minimizes the risk of nutrition-related chronic disease. | **1, 2** |
| | • Launch an interactive feature on the Health Canada website to provide information on the Nutrition Facts table found on food labels and help consumers make more informed food choices. | **1, 2** |
| | • Ensure that nutrition considerations and labelling information are integrated into key national and international campaigns and strategies. | **1, 2** |
| | • Distribute nutrition guidance information and the results of the Total Diet Study. | **1, 2** |

| Themes | Highlighted Plans | KPI |
|---|---|---|
| *... on dietary reference intakes* | • Work with the U.S. Institutes of Medicine to produce and widely disseminate a report of the Dietary Reference Intakes to Canadian practitioners to help guide nutrition policies and programs. | **1, 2** |
| *... on adverse reactions* | • Distribute the Canadian Adverse Reaction Newsletter to more than 64,000 physicians across Canada and around the world. | **1, 2** |
| *... on natural health products* | • Continue to develop research networks on herbal medicines and natural health products in collaboration with the Canadian Institutes of Health Research and the Institute of Aboriginal People's Health. | **1, 2** |
| *... on the safe disposal of pharmaceuticals* | • Distribute fact sheets on new topics such as the safe disposal of pharmaceutical products. | **1, 2** |
| *... on HPFB's scientific and regulatory work* | • Publish the Summary Basis of Decisions that outline the rationale and scientific basis of our regulatory decisions concerning market authorization of new drugs and medical devices for human use. | **1, 2** |
| | • Launch a Notice of Compliance database which will allow Canadians to search information about all drugs since 1994. | **1, 2** |
| | • Distribute fact sheets about HPFB's regulatory role and activities. | **1, 2** |

# *Public and Stakeholder Involvement – Highlighted Plans*

*We will continue to increase our efforts to inform, engage and consult with Canadians and our stakeholders in policy development and decision-making on the safety and effectiveness of health products, the safety and nutritional value of food and dietary guidance for Canadians.*

**Key Performance Indicators (KPIs)**

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

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Engaging Canadians** | HPFB will continue to seek new ways to give Canadians and stakeholders the opportunity to have their say on important health product, food safety, and nutrition issues, while ensuring timely regulatory decisions and progress. For example, we will: | |

| | | |
|---|---|---|
| | • Implement a new public involvement framework to ensure our public involvement activities are efficient and effective. | **1, 2, 3, 5** |
| | • Increase our use of online consultation tools to solicit more immediate and valuable information from Canadians and health stakeholders on many aspects of our business, such as the revision of *Canada's Food Guide to Healthy Eating*. | **4** |
| | • Engage the public, industry and other stakeholders to solicit policy and regulation input in areas such as blood and blood components, new drug delivery methods and the development of a regulatory framework for environmental assessments. | **1, 3, 5** |
| | • Begin operations of a new Office of the Public Ombudsman to handle complaints, concerns and feedback from individuals and organizations about our work. | **1, 2, 3** |
| | • Hold public fora on COX-2 inhibitors and breast implants. We will establish leading edge practices in public engagement that will include use of an extensive online site for public submissions, and public access to industry information in an earlier timeframe and more accessible format than other regulators. | **1, 2, 3,4, 5** |
| | • Create a permanent health products safety board, which will include external members and incorporate principles of openness and transparency in its terms of reference and operations. | **1, 3, 5** |
| | • Conclude national consultations on the registration and disclosure of clinical trial information as well as a national survey of users. | **1, 3, 5** |
| | • Launch a national consultation on mandatory reporting of Adverse Drug reactions. | **1, 3, 5** |
| **Stronger partnerships** | HPFB will continue to strengthen its relations with domestic and international partners, including government, industry, consumer and advocacy groups, and academia. For example, we will: | |
| | • Collect and consider feedback on the draft joint industry guidance for inhalation and nasal products developed with the European Medicines Agency, and finalize the guidance. | **5** |

# *A Strong Organization – Highlighted Plans*

*Maintaining our capacity to manage complex regulatory, scientific, public policy, public health, communications and legal considerations is critical to our success in serving Canadians. To effectively manage 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. Given that approximately 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 (KPIs)**

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

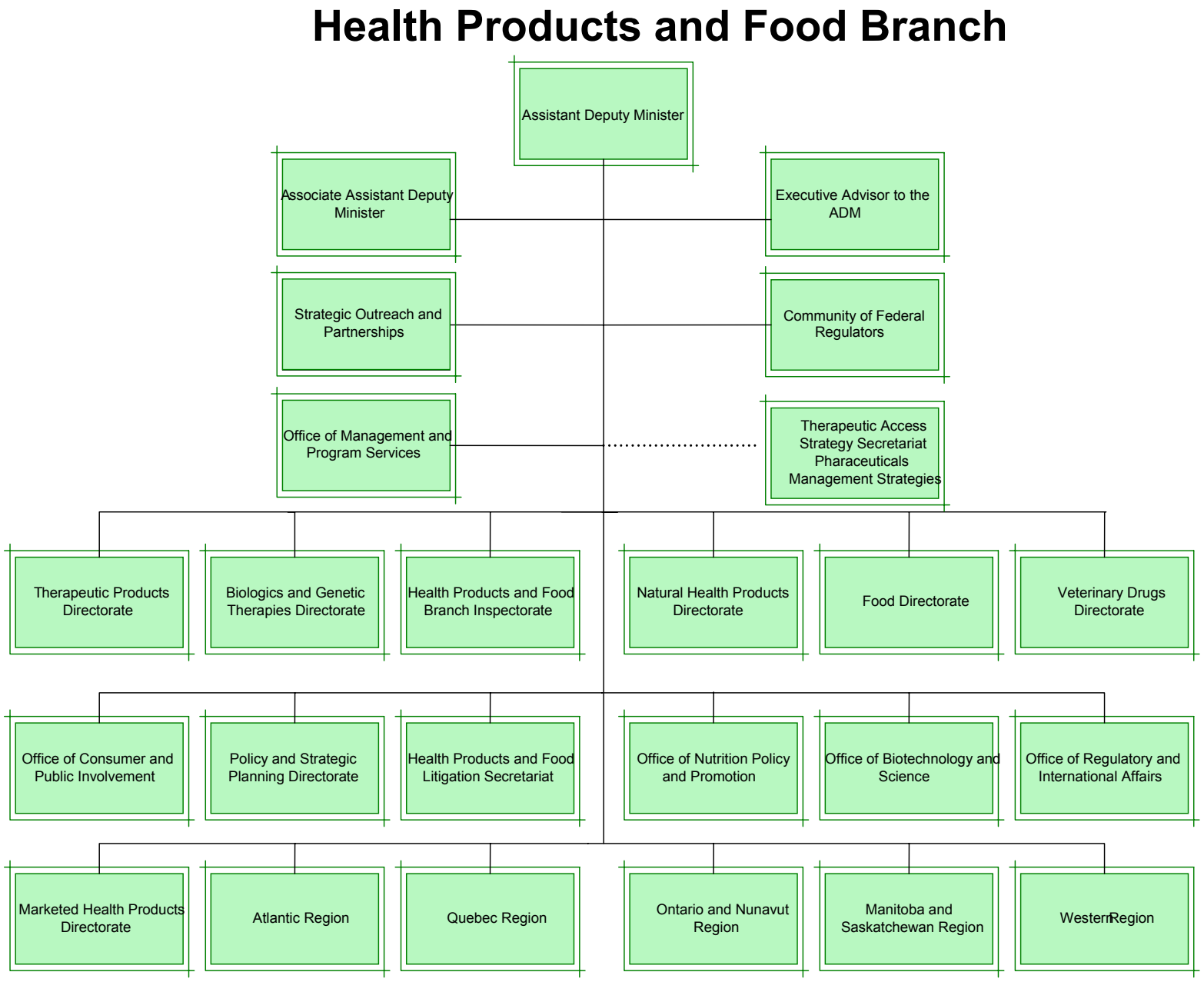
| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Emergency preparedness** | HPFB will continue to implement enhancements in biosecurity, and emergency preparedness and response capacity. Development of business continuity plans will be ongoing. | **6** |

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Human resources management** | HPFB will continue to implement employee succession, staffing, orientation, training and development plans that support Health Canada's Workplace Health and Human Resource Management Strategy.<br><br>HPFB will continue to invest in staff training to ensure we have the right knowledge and tools to do our work and engage stakeholders successfully. | **1, 2, 3**<br><br>**1** |
| **Information Systems** | HPFB will continue to enhance our database systems and infrastructure to better manage information for our changing needs. This will strengthen our capacity to track information on ingredients contained in therapeutic products to ensure they are sourced from BSE-free animals as well as track products that have been approved under the Access to Medicines Program for developing countries.<br><br>We will also continue work to achieve efficiencies by consolidating our information technology functions, equipment and infrastructure. | **2, 5**<br><br>**5** |
| **Planning and performance** | HPFB will continue to develop plans and performance frameworks that better position us to successfully meet our goals. For example, we will:<br><br>• Initiate the development of a new program activity architecture, an updated strategic plan and improved performance frameworks.<br><br>• Develop an external charging regime for therapeutic products, as part of a longer term, sustainable funding strategy. | <br><br>**4**<br><br>**1** |

| Themes | Highlighted Plans | KPI |
|---|---|---|
| **Stronger audit and evaluation** | HPFB will strengthen its audit and evaluation capacity to continually monitor and shape efficiency and effectiveness improvements. For example, we will:<br><br>• Develop an evaluation framework for BSE Initiatives and a performance framework for the Access to Medicines Program.<br><br>• We will carry out formative evaluations of BSE and Therapeutics Access Strategy, as well as a summative review of the Canadian Regulatory System for Biotechnology. | **4**<br><br>**4** |

# *Appendix 1: How We Are Organized to Deliver Results*

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.



| Organization Unit | Mandate |
|---|---|
| **Assistant Deputy Minister's Office** | Advises the Minister, manages parliamentary relations, correspondence and briefing materials, and identifies and manages high visibility risk issues. |
| **Biologics and Genetic Therapies Directorate** | 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

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

Biotechnology
http://www.hc-sc.gc.ca/sr-sr/biotech/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

Security and Prosperity Partnership of North America
http://www.fac.gc.ca/spp/spp-menu-en.asp

Trilateral Cooperation Charter
http://www.hc-sc.gc.ca/fn-an/intactivit/trilateral-coop/charter_charte_e.html

Regulatory Review of Pharmaceuticals, Biologics and Medical Devices – 2004 Annual Summary of Performance
http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/performance_rendement_2004_e.html,