



Health
Canada

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*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

2007-12

Health Products and Food Branch
Strategic Plan

*Protecting and Promoting the Health
and Safety of Canadians*



Canada

2007-12

Health Products and Food Branch

Strategic Plan

*Protecting and Promoting the Health
and Safety of Canadians*

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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Assistant Deputy Minister's Message



Neil Yeates
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

I am pleased to present the Health Products and Food Branch's *2007-12 Strategic Plan*, which will guide our work over the next five years.

Health Canada plays a key role in protecting and promoting the health of Canadians. Since its creation in 2000, the Health Products and Food Branch has evolved and adapted to meet new and increasingly complex challenges.

Our last strategic plan was a major milestone for the Branch. It identified five key strategies to ensure that Canadians have timely access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices. We have made significant progress in achieving the commitments under each strategy over the last three years. An overview of key achievements is provided on page 3.

While we celebrate these achievements, our work is not yet done. For example, we face challenges including:

- an informed and engaged public with higher expectations for performance, openness and transparency of its government;
- accelerating scientific, technological and medical advances in the products we regulate and how they are used; and
- globalization and the rise of transborder threats to our health and environment.

"To meet these challenges, we need to modernize our regulatory system, recognizing that now, more than ever, there is a need to anticipate, respond and be at the forefront of these challenges."

In fall 2006, we launched the *Blueprint for Renewal* to take a comprehensive review of our approach to regulating health products and food. The comments we received from our consultations with stakeholders were critical to the development of our *2007-12 Strategic Plan* and our updated *Blueprint for Renewal II*, which is being released at the same time as this plan.

Looking ahead, our new 2007-12 Strategic Plan will build on opportunities to maintain and improve the health and safety of Canadians:

- We will continue to lead the way as a trusted and respected scientific and regulatory authority.
- We want to make a greater impact internationally to ensure that the interests of Canadians are promoted.
- We will continue to be a trusted source of health information and promote conditions that allow Canadians to make informed decisions and healthy choices.

As a science-based organization, excellence in science is the cornerstone of our credibility and our ability to accomplish our mission. For the first time, we are developing a strategic science plan for 2007-12. We anticipate that over the next five years there will be major pressures on our science infrastructure, and that we will need to adapt our practices as science changes. Building on our 2003 report, *Our Science, Our Health*, the plan will guide our future work, complement our strategic plan and support us in building science partnerships across the Health Portfolio and with the national and international community.

Our *2007-12 Strategic Plan* outlines the six strategies that will guide us forward. The first five strategies will ensure that we remain a modern and responsive regulator that advances national and international collaboration, and integrates openness and transparency into its day-to-day work. Vital to accomplishing these goals is a skilled and motivated workforce. Our sixth strategy will allow us to create an environment that is focused on people and conducive to them doing their best work.

Our *Strategic Plan* reflects our continued commitment to promote and protect the health and safety of Canadians. Working with stakeholders, partners, Canadians and our dedicated staff, HPFB looks forward to implementing these key strategies to achieve our vision.

Our Science, Our Health

Copies of our 2003 science report are available on our Web site at www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/our-notre_sciences_03_07_e.html



What We Achieved in 2004-07

- Through the Therapeutics Access Strategy launched in 2003, we improved the efficiency of the drug review system substantially—we streamlined the pre-market review process and eliminated our review backlog in pharmaceuticals and biologics.
- We made available new databases, such as MedEffect and the Notice of Compliance, on Health Canada's Web site to provide Canadians with access to the latest advisories, warnings and recalls for health products and to other valuable drug information.
- We released the revised *Canada's Food Guide*, which provides Canadians with reliable information on healthy eating and serves as the basis for nutrition and health policies and programs across Canada.
- We revised and updated the Safety Assessment of Novel Foods to incorporate international guidelines for assessing novel foods of microbial and plant origin. We also continue to promote the new nutrition labelling requirements for food products and how food labels can be used to make healthy choices.
- We strengthened the safety system for drugs and other therapeutic products and increased our compliance and enforcement activities.
- We increased the transparency, openness and accountability of our regulatory decision making by engaging in numerous national consultations each year and making more information available to the public about how we make our regulatory decisions.
- By fostering strong partnerships and sharing information with regulatory counterparts in Canada and around the world, we enhanced our ability to protect the health and safety of Canadians.

Further examples of our achievements are detailed in our *Progress Report on the HPFB 2004-07 Strategic Plan*.

Our Vision, Mission and Values

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.

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.

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.

Who We Are

The Health Products and Food Branch is Health Canada's authority responsible for regulating health products and food through the *Food and Drugs Act*.

What We Do

We evaluate and monitor 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.

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 multi-disciplinary 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.

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:

We uphold Health Canada's three core values

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

- 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.

Emerging Challenges

The Health Products and Food Branch continues to provide Canadians with timely access to safe and effective health products and a safe, nutritious food supply. However, we recognize that the issues we deal with are becoming increasingly complex, are rapidly changing and have far more profound implications.

Today more than ever, we need to anticipate and respond quickly to emerging challenges and seek new opportunities to ensure that our effectiveness as a science authority and modern regulator continues to serve Canadians. Some key emerging challenges facing the Branch include:

Rising rates of obesity

The World Health Organization projects that by 2015, approximately 2.3 billion adults will be overweight and over 700 million will be obese.

Overweight and obesity lead to serious health consequences and are major risk factors for chronic disease such as:

- Cardiovascular disease, mainly heart disease and stroke
- Diabetes
- Musculoskeletal disorders, mainly osteoarthritis

Foodborne pathogens - They are micro-organisms such as salmonella, campylobacter and e.coli that cause disease

Public health

Canadians are facing unprecedented challenges and threats to their health that are dramatically increasing health care costs, disability and in some cases premature deaths:

- Rising rates of obesity and chronic diseases, such as cancer, type II diabetes, and cardiovascular disease.
- The spread of communicable diseases such as HIV-AIDS and severe acute respiratory syndrome (SARS); the potential spread of avian influenza and the West-Nile virus; the threat of new influenza pandemics – facilitated by increased trans-border movement of people and goods.
- A resurgence of old diseases, such as malaria and tuberculosis and new strains of old diseases, such as cholera and meningitis.
- Declining fertility rates, and increasing life spans with more seniors expecting better quality of life.
- An increase in the emergence of dangerous **foodborne pathogens**, such as *Salmonella*, including those that can cause acute and chronic illnesses.

Globalization

Globalization of trade has brought many benefits as well as concerns to Canadians. Open markets have blurred the boundaries between nations and increased the complexity of regulatory issues.

Emerging challenges include:

- An increased reliance on international cooperation to ensure regulatory alignment, and to prevent and combat the spread of infectious diseases.
- A requirement to engage in collaborative approaches at a national and international level
- The need to maintain the integrity and bio-security of our food supply and ensure international trust in the quality and safety of Canadian food products.
- New security issues, such as the threat of bio-terrorism.

Environment

Increasing environmental issues are affecting the health of Canadians and the safety of food and the food supply:

- Global warming and its potential impact on the food supply.
- Global water scarcity and changes in the ecosystem; new pests in the food supply.
- Air pollution and its impact on human health—such as the exacerbation of asthma and respiratory diseases—and its impact on vegetation, animal health and marine environments in the food supply.
- A thinning ozone layer and its potential link to increased cancer rates.
- Use of veterinary drugs and their impact on soil and water.
- Changing social and physical environments that affect healthy eating choices of Canadians.

Science and technology

Rapid advances in science and technology hold tremendous potential for improvements to the health and quality of life of Canadians—through more effective cures and prevention or improvements in health care systems and our physical environment. However, many challenges exist:

- Product safety concerns – new technologies are quickly applied to consumer products, food and drugs.

Nanotechnology is a field of applied science and technology that crosses many disciplines; it refers to building devices from single atoms as well as controlling matter on a scale smaller than a micrometer.

Did you know?

By accessing the Branch's latest and best information on health products, nutrition and food, Canadians can make informed choices to maintain and improve their health outcomes, contributing to a healthier Canada.

- [MedEffect Web site](#)
- [Canada's Food Guide](#)
- [Involving You newsletter](#)
- [Canadian Adverse Reaction Newsletter](#)
- [It's Your Health Web portal](#)

- Rapid advances increase strain on our monitoring and assessment activities – there is a need to reduce risks while enabling access to benefits.
- Potential impact of new fields of science and technology on health, for example the health effects of **nanotechnology**.

Public engagement

Canadians are better informed, value choice, and are becoming increasingly involved in making decisions about their health, from the food they eat to the treatments they seek. While Health Canada provides access to safe health products and a nutritious food supply, there are many challenges:

- A growing concern about the safety of products once they are on the market.
- Readily accessible, reliable and comprehensive information on the health benefits and risks of products.
- An overwhelming amount of information on the Internet from many sources, some of which can put Canadians at risk.
- Less tolerance of government inefficiencies; higher expectations of government's performance standards, accountability and transparency.
- A better informed public that is more willing to challenge government decisions.

Regulatory system

Health Canada's current regulatory approach has evolved incrementally over the past 50 years to keep pace with changing requirements, including advancing health policy goals.

Specific regulatory challenges include:

- An outdated regulatory toolkit that is increasingly limited and inflexible in responding to today's health products and food environment and is falling behind international best practices.
- A system that is passive, activated by events rather than influencing outcomes.

- The system's current incapacity to consider a given product through its entire life cycle – from discovery to examining the “real world” benefits and risks of a health product on the market.
- A system that is limited in its ability to obtain post-market information on a product's safety and detect emerging risks, and in its authority for compliance and enforcement.
- The need for an efficient, effective and responsive approach to pre-market evaluation for food products.
- A system challenged in its ability to enable increased transparency and openness – a balance between the need for the public to have sufficient information to make informed choice and the protection of intellectual property rights, and personal health information and privacy.
- A system that currently works in isolation from the health care and research and development systems, which significantly impedes its overall effectiveness.

Our Progress

Facing increasingly complex public health and environmental issues, science and technology advances as well as increased expectations of openness, transparency and accountability from Canadians, our regulatory system now requires significant and profound change if it is to be flexible, adaptable, sustainable and responsive, while maintaining Health Canada's high standards for safety.

In October 2006, the Branch released the discussion document *Blueprint for Renewal* to communicate our current thinking with respect to the modernization of the regulatory system for health products and food. The comments we received from our consultations with stakeholders were critical to developing our *2007-12 Strategic Plan* and our updated *Blueprint for Renewal II*.

The ten key objectives and related initiatives in the Blueprint are directly linked to the six strategies in our *2007-12 Strategic Plan*. A crosswalk linking the two documents is presented on pages 21-22.

About the Blueprint for Renewal II

From October to December 2006, HPFB consulted stakeholders and the general public on the Blueprint plan. This included a series of discussion sessions across Canada, as well as an electronic consultation.

Overall, we received strong support from Canadians with respect to the case for renewal and orientations in the Blueprint. We committed to not only prepare reports of what we heard during the consultations, but also to incorporate this input into a revised version of the Blueprint.

Blueprint II fulfills this commitment. It offers a more comprehensive articulation of our action plan and how we will concretely move forward to design a regulatory system that will further protect the health and safety of Canadians.

Our 2007-12 Strategies

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.



A lifecycle approach

Health products have a lifecycle: prior to being released, there is research and development, clinical trial phases, regulatory approval and market authorization. Only after successfully completing these phases can the product be used in the "real world."

The first two strategies will ensure that we remain a modern and responsive regulator for health products and food. Strategy 1 represents a significant shift, as we adopt a **lifecycle approach** to regulating health products. Strategy 2 highlights our efforts to modernize our regulatory system for food as well as our continued commitment to promote health through a proactive approach to nutrition.

Strategies 3 and 4 focus on strengthening national and international collaboration to increase our capacity and effectiveness. Strategy 5 will allow us to better integrate transparency, openness and accountability into our day-to-day work – how we conduct ourselves internally and with our partners, stakeholders and Canadians.

Vital to accomplishing our goals is a skilled and motivated workforce. Strategy 6 will allow us to carry out our mission and deliver on all of our strategic initiatives.

1

Adopt a lifecycle approach to regulating health products

The Branch needs a more flexible, effective approach to regulating health products that will address its current challenges:

- limited authorities and tools to effectively monitor the safety of products once they reach the Canadian market; and
- inadequate tools to strengthen compliance and enforcement activities.

Health Canada will transform its current “point-in-time” approach to one that monitors a product through its lifecycle.

This fundamental shift will not only improve our effectiveness but also how we conduct our work. It will allow the Branch to assess the safety, efficacy and quality of products before, during and after their introduction to the Canadian market, and therefore provide an increased body of knowledge, improving decision-making and enhancing risk management.

Key strategic actions

- Establish and implement a **progressive licensing framework** for pharmaceuticals and biologics, and apply a lifecycle approach to other regulatory frameworks, as appropriate.
- Review the *Natural Health Products Regulations* and implement changes as required.
- Develop and implement new regulatory frameworks for vaccines, radiopharmaceuticals and blood, and for the safety of cells, tissues and organs for transplantation.
- Strengthen post-market activities, including the surveillance and monitoring of safety and therapeutic effectiveness.
- Implement a new compliance and enforcement strategy for health products, including updating tools and approaches.
- Establish a system for product categorization that is based on risk and consistent across all product lines.
- Anticipate and respond to issues at all stages in the lifecycle of a health product, including its development and post-market stages.

Did you know?

Patients and consumer groups are increasingly requesting access to experimental drugs that have not been fully tested for safety and effectiveness but that may offer hope for those with life-threatening and/or debilitating medical conditions.

Progressive licensing framework

With progressive licensing, the Branch will be able to build knowledge about a health product over its lifecycle in order to maximize its benefits and minimize its risks.

The framework will include amendments to current regulations as well as development of new guidance and regulations.

Did you know?

Natural health products include vitamins, minerals, traditional medicines, medicines made from plants, bacteria and fungi, probiotics, amino acids and essential fatty acids (such as Omega-3).

- Continue to meet or exceed internationally benchmarked performance targets for reviewing drugs, biologics and medical devices; and establish and meet performance targets for reviewing veterinary drugs and natural health products.

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

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

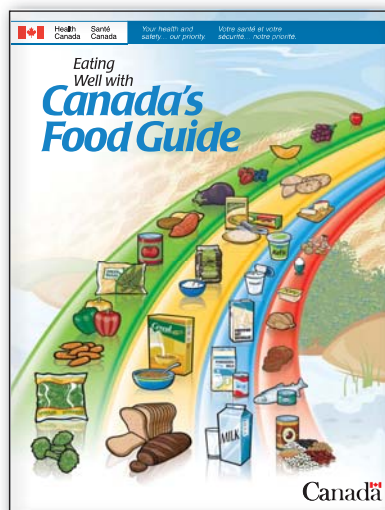
Fundamental determinants of the health and well-being of Canadians include having physical and economic access to safe and nutritious food, as well as social and physical environments that support healthy eating. In order to improve and maintain the public's overall health, the Branch needs to support Canadians in their efforts to manage their health. This includes:

- providing timely, accessible and accurate information on healthy eating and the nutritional value of food in order to foster informed and healthy choices; and
- ensuring that nutrition considerations are integrated into health, agriculture, education, social and economic policies and programs.

Did you know?

Canada's Food Guide has provided Canadians with guidance for healthy eating for over 65 years. It is also the Government of Canada's second most frequently requested document.

The Branch released the latest edition in February 2007.



The Branch also needs to modernize its policies and practices to better meet new challenges to the safety and nutritional quality of our food supply. For example, we need policies and practices that recognize the microbiological or chemical contaminants that can be present in foods, such as food additives and veterinary drug residues found in animals.

We also need to modernize our current approach to regulating food to be more effective in meeting the food safety and nutrition challenges facing Canadians, and to provide clear direction on government requirements for market access. Our approach must also ensure that Canadians can trust that claims, advertising and other information about food sold in Canada are accurate and true.

Key strategic actions

- Improve the pre-market review process for food and veterinary drugs with a focus on transparency, predictability and responsiveness.
- Implement regulatory frameworks that maximize the safety and nutritional quality of the Canadian food supply and promote food innovation and informed choice.
- Implement the foodborne contaminants initiative of the Government's Chemicals Management Plan.
- Develop and implement a strategy to address emerging threats to food safety.
- Identify and monitor patterns of healthy eating; establish policies and standards to support healthy eating and the safety and nutritional quality of the food supply.
- Inform Canadians on healthy eating to improve their health.
- 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**.
- Identify challenges in the social and physical environments of Canadians that prevent healthy eating and develop evidence to support and advance the change required to overcome these challenges.

Food-to-health pathway

It includes all the components that lead from food production and consumption to their impact on the health of Canadians.

Key results

- The Branch's oversight for 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

Advance international cooperation and be an international leader

Collaboration with international regulators and health organizations helps the Branch increase its capacity and effectiveness. Health Canada's participation internationally will ensure that we keep up with fast-paced technological advances while providing timely public access to important new therapies, health technologies and health information.

By cooperating with international regulators, we can become more efficient and effective in our decision making and more quickly identify risks associated with health products and food on the market. We are also better able to anticipate, assess and prepare our response to global health trends and issues. When collaborating with countries with developing regulatory systems, we can contribute to mitigating their health risks. This ensures that we can better protect the health and safety of Canadians from dangers related to importing health products and foods and diseases from those countries. Supporting the development and implementation of global health strategies also helps to advance our priorities at home.

Key strategic actions

- Set priorities to ensure a focused approach to international cooperation.
- Build and enhance strategic networks to advance international cooperation and scientific collaboration.
- Develop and implement a strategy for working with international partners on a bilateral and multilateral basis.
- Identify and address impediments to harmonization.
- Identify key areas of Canadian expertise and excellence to improve our international partnerships and provide leadership.

Key result

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

4

Establish strategic partnerships to fulfill our mandate

Recognizing that Health Canada is one of many contributors sharing responsibility for the health and safety of Canadians, we need to continue to be a trusted partner with other individuals and organizations sharing that responsibility. Working with provinces, territories, health care providers, and consumer and patient groups will help us increase our effectiveness. Collaborating through partnerships or information-sharing arrangements with health researchers will increase our capacity and supplement in-house expertise.

Key strategic actions

- Develop an approach to partnering, which includes defining objectives, roles, responsibilities and key results.
- Establish partnerships to improve the way we collect, assess and disseminate safety and effectiveness information for health products, food and nutrition, including a federal-provincial-territorial national network of centres of clinical evaluation excellence.
- Develop and implement a *2007-12 Strategic Science Plan* to advance our science priorities and build science capacity. Use it to strengthen our scientific partnerships in Canada, including with the Canadian Institutes of Health Research.
- Strengthen cooperation with federal-provincial-territorial organizations as well as non-governmental organizations in the health system.

Key result

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

5

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

Health Canada is committed to a more open and transparent regulatory system in which the involvement of patients, consumers, health professionals, industry and researchers contributes to better overall quality of decision making.

Public and stakeholder confidence and engagement in our regulatory work is critical to our ability to promote and protect the health and safety of Canadians. They must:

- be able to trust that the decisions we make are evidence-based and in the public interest;
- have the opportunity to, where appropriate, provide input into the decision-making process, so that the resulting decisions are of a high quality; and
- be confident that the information we provide on health products, food, nutrition and new innovations is credible, authoritative and meets their needs.

An increasingly interconnected and global environment also means we need to build stronger relationships with a more diverse range of stakeholders. The approach Health Canada is taking to engage stakeholders on issues affecting children is being tested as a model to engage others on regulatory issues for specific populations in the future.

Did you know?

Specific populations, such as children, the elderly and pregnant or nursing mothers, can react quite differently to drugs and health products, because of their age, gender, and related physiological and metabolic differences. The needs of specific populations must also be considered in safety evaluations and risk assessments for foods.

Key strategic actions

- Increase openness and transparency in our decision making by implementing new legislative and policy tools.
- Develop and implement strategies to provide Canadians with timely and accessible information they can trust on health products, food and nutrition to make healthy and informed decisions.
- Strengthen our leadership on a range of health and safety issues affecting specific populations for food, nutrition and health products.
- Implement an approach for the registration and disclosure of clinical trial information that is consistent with international practices.
- Implement the Branch's policy on public input into the review of regulated products.
- Involve stakeholders and the public early, consistently, at different points in our decision-making process.
- Integrate their input in new and more collaborative ways.

- Develop and implement new strategies that enhance information-sharing with partners, stakeholders and the public.

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 work of the Branch and in the regulatory system.



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

The Branch needs a committed, motivated, skilled and highly qualified workforce to:

- achieve its strategic goals;
- maintain its high level of performance;
- sustain and strengthen its scientific knowledge base; and
- remain on top of new approaches for regulating food and health products and promoting health.

Now, more than ever, we need to create an environment conducive to retaining and developing our talent and attracting a next generation of engaged employees. We need an environment that provides challenging and exciting work and recognizes the contributions of its people. We also need to have an up-to-date information technology infrastructure and the best tools to accomplish our work.

Key strategic actions

- Develop and implement an integrated strategy for information management and information technology that meets current and future needs of the Branch.
- Build and sustain a highly-skilled, adaptable and motivated workforce through effective recruitment, development and retention strategies.
- Strengthen the Branch's laboratory infrastructure, including reinvestment and quality management accreditation.

- Strengthen the Branch's financial management, and implement a new cost recovery framework.
- Enhance the Branch's emergency preparedness, including its ability to respond to threats to the health of Canadians.
- Through collaboration, strengthen the way the Branch programs are delivered in the regions.

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.

The Way Forward

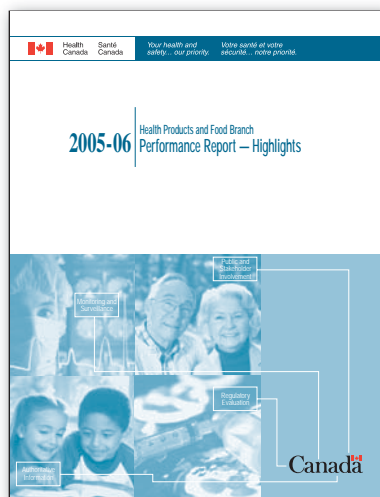
Measuring our performance

Each of the six strategies outlines key actions and results that will direct our work over the next five years. We are committed to demonstrating tangible, specific results against each key action. We will be monitoring and measuring our progress against performance indicators and specific targets.

As the plan covers the next five years, we will need to be flexible and responsive to evolving requirements and challenges. To do this, we will periodically review our key strategic actions and results to ensure they remain relevant and effective.

We will report progress made on the strategies and their activities on a yearly basis through various planning and reporting documents, including the Branch's annual *Performance Report* and *Business Plan*.

Our Annual Performance Report for 2005-06 can be found on our Web site at www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/perfreport_2005-2006_rapportrendement_e.pdf



A Crosswalk Between Our 2007-12 Strategic Plan and Blueprint for Renewal II

OUR 2007-12 STRATEGIES

1

Adopt a lifecycle approach to regulating health products

2

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

BLUEPRINT ACTIVITIES

Objective 1. Adopting product lifecycle approaches

- Progressive licensing framework for pharmaceuticals and biologics
- Review of the Special Access Programme
- Review of the regulatory framework for clinical trials
- New regulatory frameworks for blood; for human cells, tissues and organs; for vaccines; and for radiopharmaceuticals

Objective 2. Regulatory interventions proportional to risk

- Improved product categorization system
- Review of the *Natural Health Products Regulations*

Objective 3. Strengthen compliance and enforcement

Objective 5. A proactive and enabling regulatory system

- Regulatory foresight program and guidance
- Scientific and regulatory advice to industry
- Meeting internationally benchmarked performance targets for all regulated products

Objective 6. A stronger post-market surveillance system

- Strengthen post-market authorities
- Establish Canada Vigilance system
- Active surveillance systems
- Increase scientific capacity to assess safety signals
- Establish an expert advisory committee on health product vigilance

Objective 7. More emphasis on specific populations

- Establish a Paediatric Expert Advisory Committee

Objective 4. A modernized regulatory approach for food safety and nutrition

- Regulatory Modernization Strategy for Food and Nutrition
- Framework for health claims for food
- Improved pre-market processes for food additives and novel foods
- Establish flexible mechanisms to list Maximum Residue Levels for veterinary drugs

A Crosswalk Between Our *2007-12 Strategic Plan* and *Blueprint for Renewal II*

OUR 2007-12 STRATEGIES

BLUEPRINT ACTIVITIES

3

Advance international cooperation and be an international leader

Objective 10. Moving to an integrated system

- Align the regulatory system with international best practices, and where it is in Canada's interest, harmonize with other countries or international organizations
- Develop international worksharing arrangements

4

Establish strategic partnerships to fulfill our mandate

Objective 6. A stronger post-market surveillance system

- As part of the National Pharmaceuticals Strategy, develop a federal-provincial-territorial business case for a national network of centres of excellence to strengthen post-market surveillance of safety and effectiveness
- Establish partnerships to improve collection, assessment and dissemination of safety and effectiveness information

Objective 10. Moving to an integrated system

- Improve communication and collaboration with the Patented Medicine Prices Review Board and the Common Drug Review

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

Objective 8. Increased transparency and openness

- Implement Branch's policy on public input into the review of regulated products
- Implement approaches for the registration and disclosure of clinical trials
- Ongoing consultations on the Blueprint for Renewal and its various initiatives

Objective 9. More and better information about health products and food

- Develop a consumer information strategy and an outreach strategy

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

Various objectives

- Accelerate legislative changes through Health Canada's legislation renewal initiative
- Develop a new cost-recovery regime for the Branch
- Implement electronic review systems