

Health Products and Food Branch:

**Serving Canadians through a science-based
regulatory approach to health products and food**

2016-2021 Strategic Plan

Message from the Assistant Deputy Ministers

This *2016-2021 Health Products and Food Branch Strategic Plan* is the product of collaboration across all levels and disciplines within the organization, as well as with key external stakeholders. In establishing our vision and strategy for the next five years, we have endeavored to leverage all of the diverse strengths, experiences and aspirations of our team. As a result, we should all see ourselves in various aspects of this Plan, support each other in its implementation, and share in the satisfaction of its achievements.

A decade and a half into the 21st century, we continue to grapple with forces that are no longer new, but which continue to reshape the world around us. Globalization and the rapid expansion of information-sharing technology have become established facts of life, while Canada's population continues to evolve both socially and demographically, as do its health needs and expectations. To continue building and leveraging the expertise, credibility and influence necessary to protect the safety and effectiveness of health products and food in Canada, as well as promote healthy choices by Canadians, we will need to move beyond recognizing and accommodating modern global trends and begin adopting and leveraging them as a core part of our business.

Against this backdrop of ongoing change, the Health Products and Food Branch (HPFB) also finds itself in a state of transformation. We have recently transferred our compliance and enforcement role to Health Canada's newly-formed Regulatory Operations and Regions Branch, while our Minister's renewed dialogue with provinces and territories, and focus on issues of pharmaceutical access and healthy eating promise to bring significant changes to the way we do business over the coming years.

Fortunately, through our hard work in recent years, we have put ourselves in a strong position to respond to both the challenges and opportunities of our evolving environment. We have successfully innovated and adapted our regulatory review processes to clear previous backlogs and introduce new, more responsive tools to raise our standard of service and provide faster access to low-risk products, generic drugs, and subsequent entry biologics.

Over the next five years, this Strategic Plan will guide HPFB's work to leverage and build on its strengths under the following four strategic priorities:

- Openness and Transparency;
- International and Domestic Collaboration;
- Organizational and People Management Excellence; and,
- An Innovative Operational Toolkit.

These four strategic priorities are aligned with the broader Government of Canada's change agenda. Through the *2015 Speech from the Throne*, the Minister of Health's mandate letter and other initiatives such as *Blueprint 2020*, the Government of Canada has made clear its commitments to priorities such as openness and transparency, innovation, international collaboration and ensuring Canadians get value for money. Specific to Health Canada, the Minister's mandate letter cites the need for "*Government and*

its information [to be] open by default. If we want Canadians to trust their government, we need a government that trusts Canadians". The letter also states that we, as an organization, should be focussed on results and should *"track and report on the progress of our commitments; assess the effectiveness of our work; and align our resources with priorities, in order to get the results we want and Canadians deserve"*. Health Canada has also been asked to *"advance pan-Canadian collaboration on health innovation to encourage the adoption of new digital health technology to improve access, increase efficiency and improve outcomes for patients"*. This demonstrates that HPFB's strategic priorities for the next five years are consistent with the Government of Canada's overall vision for the future.

We intend to move forward with the implementation of our four strategic priorities in a collaborative and transparent fashion. We will provide all members of the Branch, as well as their key external partners, the opportunity to contribute their ideas and their efforts to achieving our vision, and to monitor progress along the way. Only by working together, supporting each other and holding each other to account can we advance our ambitious agenda that sets out to provide good health and safe choices to Canadians in today's world.

DRAFT

HPFB's vision and mandate

CORE ROLE

HPFB reviews, regulates and approves the use of thousands of health products and foods vital to the health and well-being of Canadians. As a science-based regulator, we play a stewardship role that seeks to combine the best evidence with the most effective tools to protect and promote the health of all Canadians through access to safe, high quality health and food products and clear health information that is trusted in Canada and internationally.

MANDATE

Our mandate is to take an integrated approach to managing the health-related risks and benefits of 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.

VISION

Our vision is that *all Canadians achieve optimal health outcomes through access to safe, effective, high quality health products and food, and timely, relevant and useful health information.*

Our changing environment

Advances in science, evolving business practices, globalisation of food, human and veterinary health product industries, as well as increasing data availability and public expectations present a challenging environment that demands a shift in how we operate in order to adapt to these new realities. The changing nature of our environment is described below:

INCREASED EFFICIENCY REQUIREMENTS

In recent years, driven by resource constraints and an ongoing desire to improve service standards, HPFB has focused on increasing the efficiency of core business practices. This has helped us become a global leader in product review timelines and deliver good value for public money. Moving forward, it will be important to balance this focus on efficiency with dedicated investments in innovation to nourish HPFB's longer term effectiveness and avoid unintended consequences. In the past, limited budgets have sometimes led to trade-offs between core business activities and professional development. Piece-meal

additions or alterations to processes are sometimes carried out in the name of efficiency or in response to a crisis, but paradoxically, can end up decreasing efficiency when more fully examined. Reporting requirements, while designed with efficiency in mind, can become overly rigid and burdensome.

To continue delivering consistent, first-rate service to Canadians, patients, industry and provincial/territorial stakeholders in both the short and long term, HPFB must find a sustainable balance between efficiency requirements and organizational agility and flexibility. This will allow us to anticipate and plan for issues that may arise, rather than merely reacting to them after the fact.

RAPIDLY EVOLVING TECHNOLOGY, SCIENCE AND BUSINESS PRACTICES

Technology, science and business practices continue to change at a rapid pace. In addition to a high number of products entering the market, there continue to be altogether novel classes of products, innovative businesses, and evolving trends in medicine that challenge conventional definitions, classifications, and regulatory frameworks. For example, innovations in biotechnology, genomics, nanotechnology, and digital technology have put new and increasing pressure on current risk management and regulatory frameworks. HPFB staff will need to keep abreast of these changes, and need secure and reliable mechanisms to track and analyse an increasing volume of scientific, technical, health, personal and business information from patients, consumers, and other stakeholders within Canada and around the world .

When it comes to regulating new and innovative products, risk management impacts exist in almost all health product regulatory frameworks, such as when a product is subject to more than one existing regulatory framework; where data or knowledge of a product is inadequate to establish human safety; or where common terminology, testing methodology and effective assessment tools are either not agreed upon or lacking. Challenges in defining confidential business information for the purpose of openness and transparency are also tied into this rapid evolution.

To continue delivering on our mandate and remain a trusted source of health information, HPFB needs to keep pace with this evolution through continued collaboration with partners in order to enrich and build upon others' experiences, and ongoing investment in training, professional development and knowledge transfer. It will also be necessary to dedicate time and resources to innovation on an ongoing basis.

GLOBALIZATION OF SUPPLY CHAINS

Production of health products and food has become increasingly globalized in recent years. As a result, supply chains have become more complex, with many of today's health products following a multi-step (and multi-jurisdictional) path before reaching the Canadian market. As networks expand and regulated parties conduct business in non-traditional ways, it is challenging for regulators to maintain the same level of oversight, and the risks of quality issues increase. Siloed domestic regulatory agencies operating

in a globalized world is a model that is no longer tenable. To be an effective regulator in this global environment, HPFB is required to maintain global awareness and collaborative relationships with like-minded international partners to share consistent, reliable and timely information about the production, quality and short and long-term risks of health products and food entering the market.

The Canadian market is also impacted by regulatory decisions made by other jurisdictions, such as requirements to change or improve manufacturing processes at an off-site facility. This interdependency requires HPFB to keep pace with increasing volumes of information in order to support decision making and harmonise our efforts with our regulatory counterparts.

PROLIFERATION OF ONLINE INFORMATION AND INCREASING PUBLIC EXPECTATIONS

The wide availability of online information is not a new phenomenon; however, the public's awareness, reliance on and expectations of online information continue to grow. There are now an estimated 70 million websites disseminating health information and Canadians expect to be able to find relevant and useful information on all manner of health-related topics instantaneously. To protect the health and safety of Canadians and promote their healthy choices in this environment, Health Canada must be prepared to compete for credibility and influence on an ongoing basis. This puts an onus on HPFB to develop innovative communications tools to package and deliver regulatory, educational and promotional information that is timely, clear, useful, and backed by compelling evidence. This must be carried out jointly in collaboration with government counterparts who also share this responsibility.

HPFB'S CHANGING ORGANIZATIONAL STRUCTURE

Following a 2-year review of Health Canada's compliance and enforcement functions, HPFB's Inspectorate has recently been transferred to a new branch called the Regulatory Operations and Regions Branch (RORB). The new RORB will continue delivering high-quality inspection programs in partnership with HPFB, the Healthy Environments and Consumer Safety Branch, the Pest Management Regulatory Agency, as well as the Drug Analysis Program, Food laboratory programs and environmental health programs.

This organisational change recognizes the challenges of today's fast-paced global environment and the demands of Canadians for more transparency in the decisions we make. It also highlights the importance of Health Canada's compliance and enforcement role and allows us to look at ways to increase our inspection capacity including the number of foreign inspections we conduct.

The transfer of the Inspectorate to the new branch will not impact HPFB's core role as a regulator of health products and food or reduce the significance of the environmental factors outlined in this section. However, it will have process and resource implications for HPFB, and we will need to adapt

accordingly. We will continue to work closely with the RORB to ensure a seamless transition and ongoing collaboration between the two branches.

Strategic priorities moving forward

As previously indicated, to follow through with our mandate while also responding to these changing conditions and building on the progress achieved through the previous Strategic Plan, HPFB has identified four strategic priorities for the Branch over the next five years. As HPFB strives to advance these strategic priorities, our work will be guided by four core values:

- **Science Excellence** – investing in the best skills to leverage the best evidence;
- **Effective Leadership** – setting ambitious goals and marshalling the resources to achieve them;
- **Proactive Engagement** – maximizing collaboration in support of a common goal; and,
- **Focus on Outcomes**– adopting whichever approach supports the best health outcome.

Together, these values create a virtuous cycle of improvement. By working with partners to develop and leverage the very best scientific evidence, HPFB puts itself in a stronger position to lead and shape the public discourse on important health issues. Through this discourse, HPFB is better able to identify and shape the tools to achieve the best health outcomes which, in turn, attract increased collaboration of key stakeholders and potential new partners. As the cycle repeats itself, HPFB's credibility, influence and ability to protect and promote the good health of Canadians increase continuously.

Over the next five years, HPFB will strive to improve efficiencies by using risk-based resource management, improve the openness and transparency of what we do and decisions we make, expand our toolkit to take advantage of novel ways of doing business, and build on and leverage partnerships with industry, academia, health care institutions and international regulators.

This Strategic Plan represents our ongoing reassessment of how we work. Enhancements in efficiency, collaboration, innovation, and openness and transparency, are just some of the ways HPFB can improve on our strengths internally and externally. With support from and collaboration with a broad range of stakeholders, we will be well positioned to continue building on what has been accomplished.

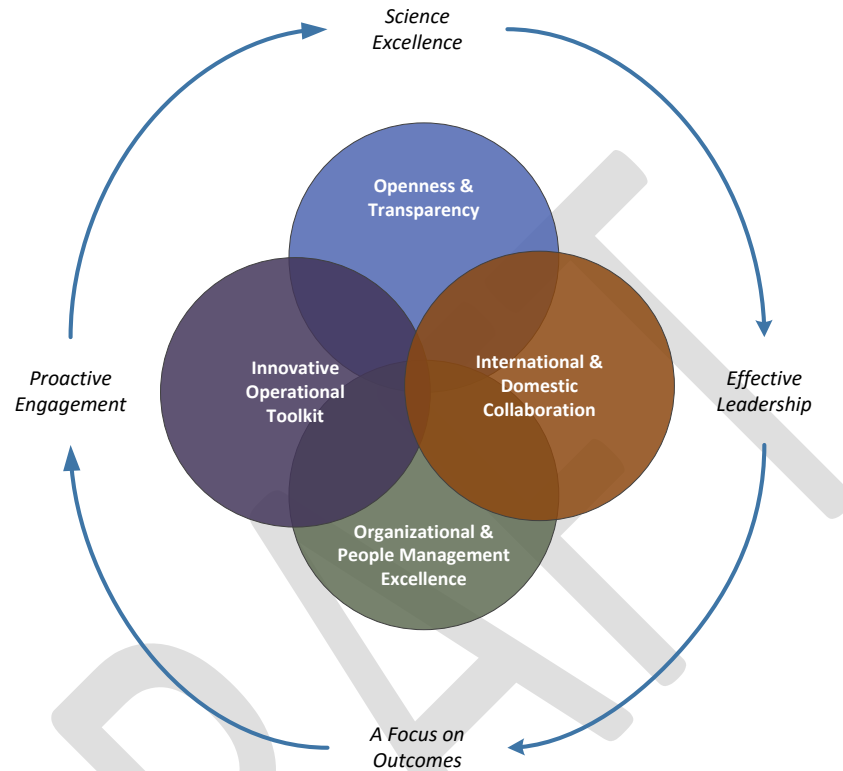
HPFB'S CHECKLIST FOR SUCCESS

Over the next five years, HPFB will adapt its work culture and tools to continue excelling in a changing environment. The success of this change agenda will be measured by the following characterizations:

- ✓ HPFB strikes a balance between maximising safety and minimising regulatory burden, through a strengthened, more efficient regulatory framework that is current and responsive to our changing environment.
- ✓ HPFB is a respected, credible source of scientific health information; providing timely and clear communication behind our positions on the wide range of decisions made daily to empower Canadians to make decisions themselves.
- ✓ HPFB is current on the latest health research and leads scientific dialogues and debates through targeted investments in our science capacity.
- ✓ HPFB maintains an ongoing dialogue with stakeholders to ensure they have a clear understanding of their regulatory obligations.
- ✓ HPFB has a more in depth understanding of Canadian consumers, behaviours and current consumption in order to provide more targeted information reflective of current trends.
- ✓ Stakeholders understand what HPFB does and does not do, through open communication of our legislation, regulations, capacities and priorities as a regulator.
- ✓ Through proactive risk management, HPFB takes a risk-based, value-added approach to our work by strategically focusing our resources where they can add the most value to achieving our mandate, and leverage strategic partnerships to support areas with less capacity.
- ✓ HPFB takes a more open approach to shaping the public narrative with targeted reports on our research and position, health topics and trends, as well as openly publicizing corrections and improvements. To effectively achieve this, approval processes for public communications are more efficient and staff have an increased ability to engage externally.
- ✓ HPFB embodies a culture that values and promotes innovation and where change is fostered through dedicating resources to develop new tools and approaches, supporting and encouraging staff to propose process improvements, and empowering them to make decisions where appropriate.
- ✓ HPFB's Information technology (IT) tools and support are more effective, modern and reliable; making it easier for staff to fulfill their responsibilities by ensuring they have the tools and support they need.
- ✓ As a leader amongst domestic and international regulators, HPFB fills gaps in research through dedicated innovation and regulatory capacity. We seek to harmonize our efforts with like-minded partners; in some cases leading the effort, in others, following the lead and expertise of like-minded partners.

THE VALUES AND PRIORITIES THAT WILL SHAPE OUR APPROACH

HPFB’s strategy for the next five years is centered on four cross-cutting themes, guided by four core Branch values.



Strategic Priority 1

OPENNESS AND TRANSPARENCY

Openness and transparency, as defined in the *Regulatory Transparency and Openness Framework (RTOF)*, have begun to underpin much of our work over recent years. Over the next five years, we will build on progress achieved under our previous Strategic Plan by adopting openness and transparency as a culture and way of doing business in our day to day work. Health and safety information, the rationale behind regulatory decisions and key data will continue to be made available in convenient formats and in a timely manner. Stakeholders will be engaged early when applicable, to encourage meaningful dialogue before decisions are made. By being more open and transparent, we will be better positioned to ensure Canadians have the information they need to make healthy choices and informed decisions about their health.

KEY OBJECTIVES

- HPFB is open about our mandate, capacities and priorities as a regulator, and is transparent about how decisions are made.
- HPFB has an ongoing dialogue with stakeholders to ensure they have a clear understanding of their regulatory obligations.
- HPFB is a respected, credible source of timely and clear scientific and health information, and is proactive in communicating our research and positions through conventional and social media, and stakeholder relationships.
- Clear guidelines are provided to staff to ensure they fully comprehend the boundaries of confidential information and privacy principles when sharing information externally.

COMMITMENTS

To build on and improve HPFB's openness and transparency, the Branch will:

1. develop a new strategy to proactively increase HPFB's influence and credibility by improving our means of interfacing with stakeholders and the public, and showcasing our expertise (e.g. scientific experts);
2. improve Canadians' access to timely, useful and relevant health and safety information regarding health products and food, while still respecting privacy, confidentiality and security considerations as part of the refresh of the *Regulatory Openness and Transparency Framework* and in support of the principles of Open Government;
3. modernize our digital presence, including on social media, and provide credible, user-centric information to our target audiences so they can make informed decisions about their food and health.

4. promote a culture of transparency that enhances our credibility by reliably exchanging information and sharing the evidence and rationale behind our positions whenever possible and appropriate.

Strategic Priority 2

INTERNATIONAL AND DOMESTIC COLLABORATION

Our operating environment is highly complex, cuts across jurisdictions, has players in a multitude of sectors, and has the potential to blur lines of responsibility and accountability for keeping Canadians safe and informed. Collaboration with partners helps to maximize outputs, modernise Canada's health product and food regulatory system, ensure that Canadians have timely access to safe and effective products, and improve the consistency and reliability of increasing volumes of information available on which to base decisions.

KEY OBJECTIVES

- HPFB takes a risk-based approach to our work, including fostering and leveraging strategic partnerships to focus resources on addressing priorities to fulfill our mandate.
- HPFB seeks to be a highly regarded regulatory leader in targeted areas, filling gaps in international research, innovation and regulatory capacity, influencing global policy, priorities and responses, and harmonizing our efforts with partners.
- HPFB engages our domestic and international stakeholders early, in meaningful dialogue and collaboration
- HPFB establishes strong, ongoing relationships to form the basis for early and meaningful dialogue with stakeholders on key issues, while being mindful of potential conflicts of interest.

COMMITMENTS

To improve our international and domestic collaboration, HPFB will:

1. establish a dedicated capacity to coordinate and enhance HPFB's collaboration with key domestic partners, namely: other government departments; other levels of government; academia; health professionals; patient/consumer groups; and industry.
2. target work with our foreign regulatory counterparts to address common challenges and issues, align our regulatory frameworks, and minimize duplication of work while maximizing safety, quality and efficacy of health products and food within the realities of our changing environment;

3. work with domestic and international partners to increase harmonisation of information management systems in order to increase efficiencies, reduce burden on information providers, analyse trends, and identify opportunities for further cooperation; and,
4. apply a risk-based approach to focus on activities that bring value to the Canadian health and food systems.

Strategic Priority 3

ORGANIZATIONAL AND PEOPLE MANAGEMENT EXCELLENCE

Optimising our internal processes and leveraging risk-based decision-making models will assist HPFB in achieving our mandate by anticipating challenges; focussing financial and staff resources proactively; being as efficient as possible; meeting our service standards; and ensuring staff are highly engaged and motivated. It will also help ensure that our interface with stakeholders is reliable, smooth, logical and efficient. Under the previous Strategic Plan, the *HPFB People Management Strategic Plan 2015-18* was established; the people component of this Strategic Priority will require leveraging and building upon that Plan under its three pillars of *Employee Wellbeing, Talent Management* and *Learning and Development*.

KEY OBJECTIVES

- HPFB dedicates resources to developing new approaches, empowers staff to innovate and fosters a culture of creativity, flexibility, and learning from mistakes.
- HPFB invests in and leverages its science capacity so scientists are up to date on current research and active in dialogues and debates.
- Decision-making authority is delegated as appropriate, rationales for decisions are communicated in all directions, and reporting mechanisms are reviewed periodically to ensure efficiency.
- Staff are supported with accessible, real-time, IT services and has streamlined mechanisms for obtaining IT tools.

COMMITMENTS

To support organizational and people management excellence, HPFB will:

1. foster an employee culture that encourages innovation, so as to encourage and reward employees and managers who nurture and bring forward novel ideas from concept through to actualization;

2. enhance our efforts to recruit talented staff, and ensure our processes support getting the best person in place in a reasonable time frame;
3. allocate resources and time for training, scientific and technical capacity building and knowledge transfer within staff operational requirements;
4. allocate resources to maintaining or improving HPFB critical infrastructure (e.g., laboratories).
5. Improve information sharing and communication channels between HPFB directorates as well as with others in the Health Portfolio; and,
6. address IT issues proactively, in a timely manner.

Strategic Priority 4

AN INNOVATIVE OPERATIONAL TOOLKIT

Consistent with the guiding principles of *Blueprint 2020*, we will seek out and leverage innovative, outcome-oriented tools to impact behaviour and provide Canadians and stakeholders with the information they need. There is also a need for better internal mechanisms to support innovative ideas and empower staff to put forward new ideas that have the potential to improve our performance. While regulation remains a primary approach to assist in protecting and promoting the health of Canadians, we will consider innovative, non-regulatory or voluntary interventions wherever feasible to fulfill our mandate.

KEY OBJECTIVES

- HPFB continues to improve and modernize the regulatory framework in order for it to be more agile, accessible and responsive to changing needs.
- HPFB maintains an extensive understanding of stakeholders' needs, and employs a variety of tools to foster an operating environment that improves the health and safety of Canadians, and leverages stakeholders to assist in the development and knowledge translation of tools and resources.
- Stakeholders are served by well-integrated IT systems, and have clear, user-friendly mechanisms to access information, expertise and tools.

COMMITMENTS

To build the Branch's innovative operational toolkit, HPFB will:

1. establish a dedicated, ongoing capacity for innovation and the development of new processes and tools, dedicated resources for monitoring and evaluation, project management and capturing lessons learned;
2. continue work under the *Regulatory Roadmap*, including updating our regulations, incorporating the principles of red tape reduction and supporting ongoing work to harmonise regulations;
3. accelerate the broader application of diverse tools and levers to protect the health and safety of Canadians and patients, including regulations, policies, education and awareness initiatives, data mining, and others;
4. focus on review processes to ensure timely and safe access to market for products, considering new and emerging threats in ensuring the safety of products for Canadians; and,
5. improve IT systems supporting HPFB's interface with stakeholders.

Bringing the strategic plan to life

The *2016-2021 HPFB Strategic Plan* will position us well to adapt to and evolve with the changes in our environment over the coming years. We cannot succeed in this alone; our ongoing evolution must be coordinated with our partners both inside and outside of government, at home and abroad. HPFB will need to communicate our work and progress proactively, using modern and effective communication tools, while building our credibility through science excellence, partnerships and open and transparent decision making. The Branch will continue to push on achieving efficiencies, process improvements, and meet performance standards, and will continue to engage with stakeholders as strategic initiatives evolve through to 2021, and beyond.

The Strategic Plan was built from the ground up by internal Branch staff and external stakeholders from all disciplines. In the interest of accountability, an Implementation Plan detailing work to bring about changes is being rolled out concurrently with the *2016-21 Strategic Plan*. Focusing on implementation will ensure that we have the systems in place to bring forward and promote great ideas, effective governance to facilitate projects, access to the tools and infrastructure to action what we have set out to do, and accountabilities to track our progress and course-correct for unforeseen challenges. In the spirit of the Branch's commitment to partnerships and openness, we commit to ongoing communication of progress under the Strategic Plan, both internally with staff and externally with stakeholders.

The *HPFB 2016-21 Strategic Plan*, coupled with the plan for action on implementation will set the course for a branch that brings the best value to all Branch employees, stakeholders and Canadians.