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Health Products and Food Branch

2005–07 Public Involvement Performance Report

Improving stakeholder trust and confidence in the regulatory system

Canada

Health Products and Food Branch

2005–07 Public Involvement Performance Report

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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Executive Summary

Transparency and opportunities for public participation in Health Canada's decision-making process have become an important issue for Canadians. They want to know how decisions that affect their health are made and want to be able to influence those decisions when appropriate. Becoming a world-class regulator means promoting a more open and transparent system, where the involvement of the public and stakeholders contributes to better overall quality of decision making and effective regulation in the public interest.

Did you know?

Canadians overwhelmingly agree (77%) that they would personally feel better about government decision making if they knew that governments sought informed input from citizens on a regular basis.

Rethinking Government 2006 – Wave 1 Report, EKOS, June 2006

The *2005–07 Public Involvement Performance Report* covers public involvement activities conducted by Health Canada's Health Products and Food Branch (HPFB) from April 1, 2005, to March 31, 2007. Throughout 2005–07, HPFB continued to engage a variety of stakeholders—health professionals, academics, patients, consumers, and industry—on important issues affecting the Branch. Including a range of perspectives in the decision-making process enhances the quality, credibility, and accountability of our regulatory decisions.

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.

2007–12 Strategic Plan, Health Products and Food Branch

HPFB's public involvement work is guided by commitments in its *2007–12 Strategic Plan* and by key policies and frameworks—for example, Health Canada's *Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* and the Branch's *Public Involvement Framework*—which set out principles for effectively involving stakeholders in the Branch's decision-making process. In 2005–07, the Branch continued to build on these by

- developing and launching the *HPFB Review of Regulated Products: Policy on Public Input* for staff, stakeholders, and the public to guide consideration of public input in the review of regulated products.

- continuing to pilot the *Voluntary Statement of Information Policy*, which seeks to increase the transparency of public involvement activities by making available information on all participants.

Health Products and Food Branch has made significant progress in increasing the transparency, openness, and accountability of

its regulatory decision making, with 180 public involvement activities held in 2005–06: 99 conducted on specific issues and 81 using ongoing mechanisms such as advisory bodies and bilateral meetings; 167 public involvement activities were held in 2006–07: 102 conducted on specific issues and 65 using ongoing mechanisms.

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

Public meetings, Web sites, surveys, focus groups, advisory bodies and workshops were all used to gather input on topics important to Canadians. For example, the Branch:

- mounted the first-ever public forums in 2005 on selective COX-2 inhibitors and silicone gel-filled breast implants, to give Canadians multiple ways to learn about the review process and the issues under consideration, as well as the opportunity to provide input;

- launched the *Blueprint for Renewal* in fall 2006 to take a comprehensive view of HPFB's approach to regulating health products and food. The comments received from consultations with stakeholders were critical to the development of the *2007–12 Strategic Plan* and an updated *Blueprint for Renewal II*; and

- conducted national, regional, and online consultations throughout 2006-07 with over 7,500 stakeholders on key components of *Canada's Food Guide to Healthy Eating.* Feedback resulted in a guide that promotes a pattern of eating that meets nutrient needs, promotes health, and minimizes the risk of nutrition-related chronic disease.

Reporting annually on how the public is involved in HPFB's work helps the Branch monitor trends over time, including the issues addressed, at what point the public becomes involved in the decision-making process, the methods used to engage the public, and the diversity of stakeholders invited to participate. Starting in 2007–08, the Branch will report its public involvement activities against key performance indicators in its *2007–12 Strategic Plan* and other departmental reporting documents. This will allows us to be more accountable to Canadians, improve relationships with stakeholders, promote successful development and implementation of decisions, and build public confidence in the regulatory system for health products and food.

Public Involvement in the Branch

What we do

The Health Products and Food Branch

To help Canadians maintain and improve their health, the Health Products and Food Branch strives to ensure that they have access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices.

The Branch's mandate takes an integrated approach to managing the 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.

HPFB's Vision for Public Involvement

The Branch will have mutually beneficial relationships with the public. While respecting our regulatory responsibilities, the Branch will be open, transparent, and accountable in our work, and integrate stakeholder input into our decisions. The Branch will improve stakeholder trust and confidence in the regulatory system.

The Branch's work affects the lives of every Canadian. As Canada's authority for regulating health products and food, the work of the Branch is significant. It

- monitors the safety and quality of the Canadian food supply; and
- evaluates the safety, quality, and effectiveness of drugs, vaccines, medical devices, and other therapeutic products, including natural health products, available to Canadians.

Office of Consumer and Public Involvement

The Office of Consumer and Public Involvement (OCAPI) supports the work of the Branch by providing information and opportunities to Canadians to become meaningfully involved in the decision-making process. OCAPI helps the Branch involve the public in its business, leading to better decisions for and by Canadians.

As a centre of expertise for public involvement, OCAPI

- develops policies and programs for the Branch in support of transparency and openness;

Our Public Involvement Objectives

To deliver more strategic, coherent, and effective public involvement activities, the Health Products and Food Branch will

1. Make public involvement an integral part of Branch strategic and operational planning so that resources can be identified and invested early on in the decision-making process.
2. Consult the public early and throughout the decision-making process to understand and incorporate the public's expectations, interests, and concerns when establishing priorities, developing policies, and planning programs and services.
3. Foster inclusiveness of all types of stakeholders and ensure that public involvement opportunities are as open, transparent, and accessible as possible.
4. Enhance the stakeholders' ability to participate effectively in public involvement activities.
5. Develop a customized public involvement plan for all significant policy and program initiatives that will determine public involvement objectives, identify opportunities for collaboration at all levels, select appropriate methods (exploring new technologies as well as using traditional methods), identify key types of stakeholders, and communicate how stakeholders' input will be used.
6. Evaluate the effectiveness of the public involvement initiatives from both the Branch's and the public's perspectives, in order to improve and strengthen public involvement activities.
7. Provide timely feedback to all participants, reflecting how public input influenced the decisions made.
8. Improve public awareness, through better exposure to and delivery of clear and understandable information about the Branch.

Public Involvement Framework, Health Products and Food Branch, 2004

- collaborates in strategic planning, based on its knowledge of the public environment, to make sure that transparency and openness are integrated into the Branch's business practices;
- partners with directorates and collaborates with stakeholders to deliver public involvement activities; and
- increases public awareness and understanding of the Branch by Canadians.

Did you know?

Every year, OCAPI supports the Branch in over 100 public involvement activities that touch a broad variety of issues, using, for example, electronic consultations, surveys, round table discussions, and forums.

OCAPI staff also develop tailored information and outreach tools that assist the Branch in reaching out and involving the public. These include

- HPFB's Stakeholder Information Management System (SIMS)—a database that allows the Branch to streamline the way it communicates with stakeholders, and contains up-to-date information on over 9,000 stakeholders;
- *Involving You*—a newsletter that encourages more informed awareness and involvement of Canadians in Branch work, which reaches over 1,300 stakeholders;
- targeted outreach mailouts from the Assistant Deputy Minister to 300 Branch stakeholders;
- programs for helping patients and consumers understand and get involved in the Branch decision-making process; and
- policies that promote and increase the transparency and openness of Branch public involvement activities, for example, the *HPFB Review of Regulated Products: Policy on Public Input* (page 9) and the draft policy on *Voluntary Statement of Information for Public Involvement* (page 6).

Voluntary Statement of Information for Public Involvement

Piloted in 2005, the Voluntary Statement of Information for Public Involvement Policy aims to increase the transparency of the Branch's public involvement activities by encouraging all participants to voluntarily provide basic information about themselves and the organizations they represent before they participate in a public involvement activity. A summary of the information can then be shared with all participants at the time of the meeting and appended to any report issued after the meeting.

The summary includes information on the organization's mandate, the scope of its membership, and the stakeholder group to which the individual or organization belongs—health professional, voluntary organization, academic community, etc. It also covers the participant's relationships, interests, or affiliations (financial and non-financial) with any other organization likely to be affected by the topic under consideration.

This policy is intended to foster better mutual understanding between the various stakeholder groups participating in Branch public involvement activities.

The role of public involvement in Branch decision making

Canadians want to make informed decisions about their health and to hold accountable those who make health and safety decisions on their behalf.

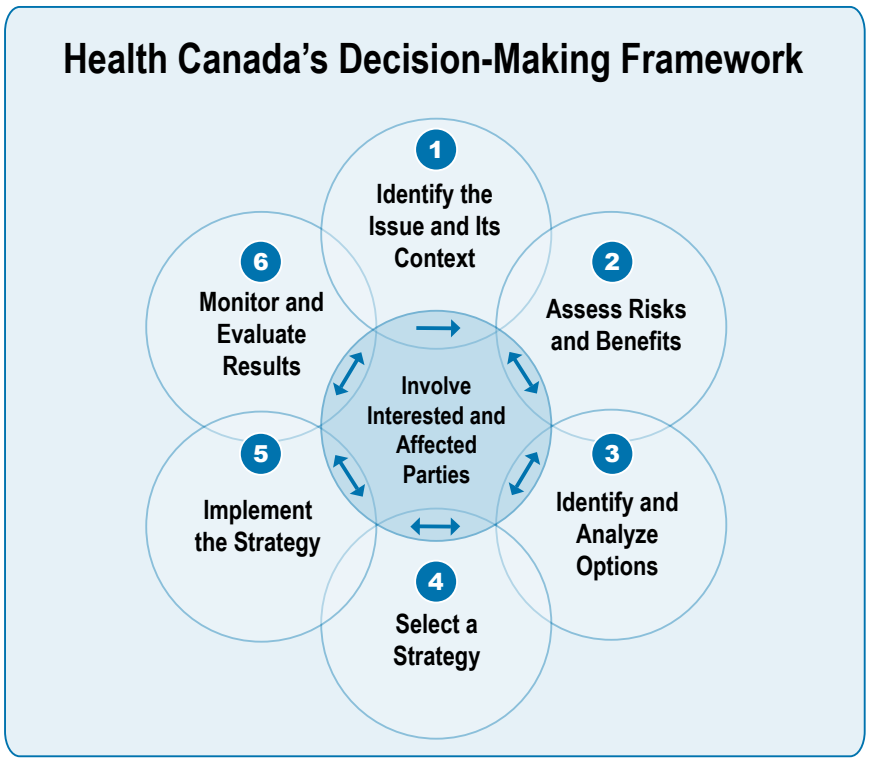
Public involvement activities offer Canadians the opportunity to have a role in Branch decision-making processes by offering their perspective, experience, and insights to understand the reasons behind Branch decisions, and to access information that allows them to make their own informed health choices.

HPFB supports federal requirements to involve the public in its decision-making processes and keep them informed about how their input is used. The *Cabinet Directive on Streamlining Regulation* states that "departments and agencies are responsible for identifying interested and affected parties, and for providing them with opportunities to take part in open, meaningful, and balanced consultations at all stages of the regulatory process."

Our work is also guided by several key frameworks, policies, and toolkits, which provide direction on public involvement for Health Canada and HPFB employees. They set out principles, guidelines, and information for effectively involving stakeholders in government decision making on health issues.

Health Canada's Decision-Making Framework

The *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* details the importance of involving interested and affected parties in the Department's decision-making processes. It is divided into six stages. Many factors, such as the level of the public involvement activity and the desired feedback, influence the decision to consult, the appropriate stage at which to carry out consultations, the extent of involvement required, and the appropriate method to use.



Did you know?

HPFB created the PIF to ensure that Branch public involvement activities are consistent, valuable, and effective. It is based on the results of extensive consultations and was launched in 2004.

HPFB Public Involvement Framework

The *Public Involvement Framework* (PIF) sets out the Branch's objectives for public involvement and incorporates the principles of transparency and openness to guide public involvement activities and to ensure that Branch decisions are made based on the best available information and evidence.

HPFB's Public Involvement Framework's Transparency and Openness Principles

Transparency

Transparency is facilitating access to and understanding of the information and processes HPFB uses to conduct its business. Transparency is shaped by these principles:

- **Equal opportunity to access information.** As much as possible, all parties who are affected by an outcome, or those who express interest in an issue, have equal access to unbiased and complete information. Access is provided through various methods including, but not limited to, making information available on the Internet.
- **Relevance.** The public receives useful and practical information that meets its needs.
- **Clarity.** Communication with the public is in clear, objective language. Whenever possible, Branch documents are written in plain language, so that the information can be understood by as many individuals as possible.
- **Accountability.** Decisions, including a rationale on how and why the decision was made, are communicated widely and promptly.
- **Timeliness.** The public receives information early enough to be aware of public involvement processes.

Openness

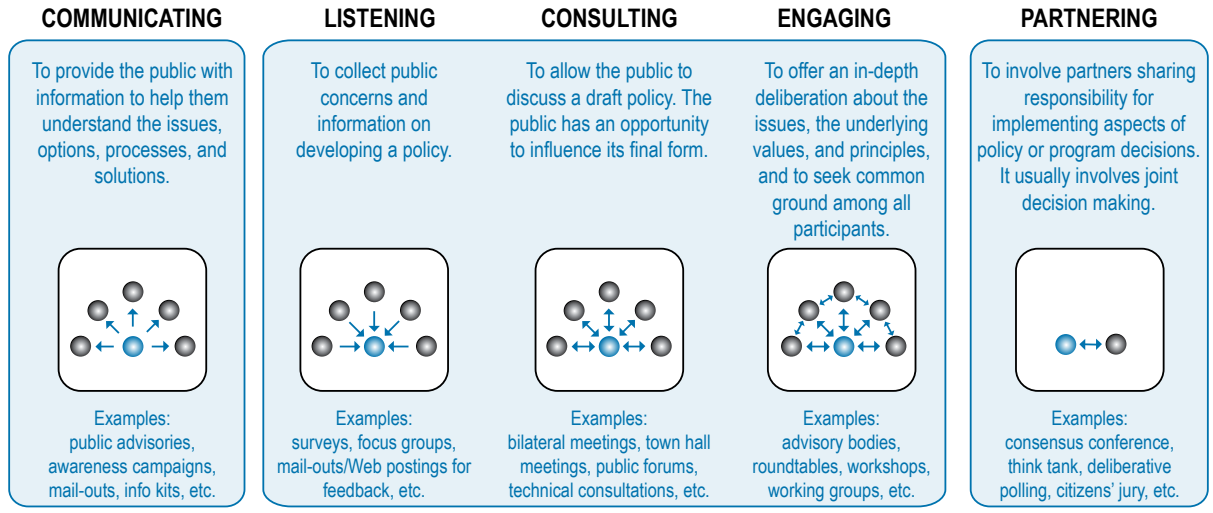
Openness is inviting, hearing, considering, and sharing information in the conduct of HPFB's business. Openness is shaped by these principles:

- **Equal opportunity for participation.** As much as possible, all parties who express an interest in an issue, or who are affected by an outcome, have an equal opportunity to influence decisions.
- **Relationship building.** The public has ongoing involvement through which it can contribute its experience, expertise, knowledge, and ideas for developing better public policies and for improving the design and delivery of programs.
- **Timeliness.** Whenever possible, the public is involved early enough in the decision-making process to be able to influence issues.
- **Planning.** Participants have enough time to prepare and to contribute effectively to public involvement.
- **Support and capacity.** Recognizing that stakeholders have differing capacities to participate in public involvement processes, measures are in place to ensure effective participation.
- **Clarity.** The purpose and objectives of public involvement activities are clearly identified. Clear roles and expectations are established and are known and understood by all.
- **Shared responsibility.** All those who participate share responsibility for successfully meeting public participation objectives and for evaluating results.
- **Accountability.** Commitments are met and outcomes are communicated.
- **Innovation.** New approaches and techniques are incorporated to encourage public participation in decision making.

The Health Canada Public Involvement Continuum

The Public Involvement Continuum, described in HPFB's Public Involvement Framework and Health Canada's Public Involvement Toolkit for Policy Making, supports flexibility as a best practice of public involvement. The continuum defines five levels of public involvement and is intended to guide the planning process by highlighting the main objectives of each public involvement level. A "toolbox" approach that supports a variety of processes, depending on the issue and point in the decision-making process, yields better input and outcomes, and can promote accessibility when broad public input is sought.

Health Canada's Public Involvement Continuum



Levels of public involvement range from communicating, to listening, consulting, and engaging, to partnering.

HPFB Review of Regulated Products: Policy on Public Input

To support its commitment to serve Canadians through quality decision making, the Health Products and Food Branch has developed the *Review of Regulated Products: Policy on Public Input*.

The policy situates public input as an important source of evidence in assessing and managing the risks and benefits associated with a regulated product. It maintains that public input enhances quality decision making in the review of a regulated product and sets out the reasons under which the Branch would seek public input in a pre-market or post-market review of a regulated product, which encompasses input from "experts," as well as from a broader

range of sources outside the conventional advisory body process. The Policy encourages the consideration of both scientific and non-scientific information that is relevant to the safety and effectiveness of a regulated product, and identifies aspects of the review process where the value of public input can be demonstrated.

Our 2005–07 Performance

Public involvement on specific issues

The Health Products and Food Branch conducted 99 public involvement activities that focused on 48 specific issues in 2005–06 and 102 public involvement activities that focused on 67 specific issues in 2006–07, compared with 84 public involvement activities in 2004–05. The majority of the issues involved policy development and the regulatory process.

Why we consulted

In 2005–07, the Branch sought the involvement of the public and stakeholders for many reasons, including to

- seek comments on proposed changes to policy and regulations;
- obtain expert opinion in relation to product reviews;
- gather input on draft guidance, directives, policies, and other documents;
- gain a better understanding of the views and behaviours of consumers;
- communicate progress, discuss issues, or identify barriers to implementing Branch initiatives;
- support stakeholders in learning more about the Branch and in participating meaningfully in our decision-making processes; and
- clarify Branch expectations and build stakeholder capacity.

Did you know?

The number of public involvement activities on specific issues at HPFB over the last three years.

2004–05: 84 activities

2005–06: 99 activities

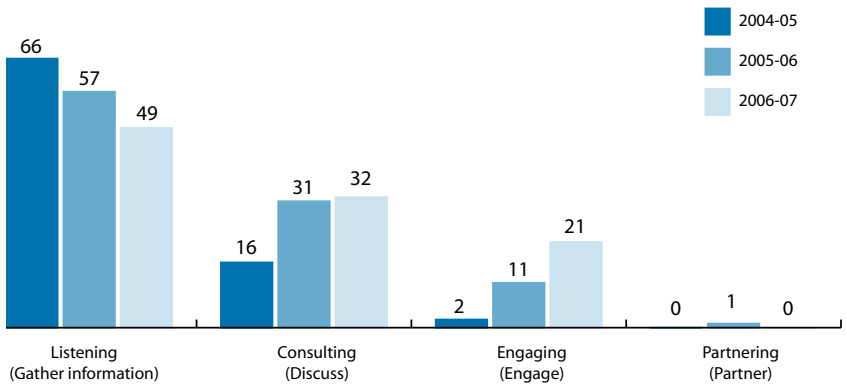
2006–07: 102 activities

How we involved stakeholders and the public in the decision-making process

When the Branch collects input from the public on specific issues, it ensures that the most appropriate method is selected based on the purpose of the activity, the desired outcome, and the availability of resources. In some cases, the Branch uses a combination of methods to collect meaningful feedback and enhance stakeholder participation.

In 2005–06 and in 2006–07, the Branch strengthened the level of public participation by increasing the total number of public involvement activities and the level of engagement.

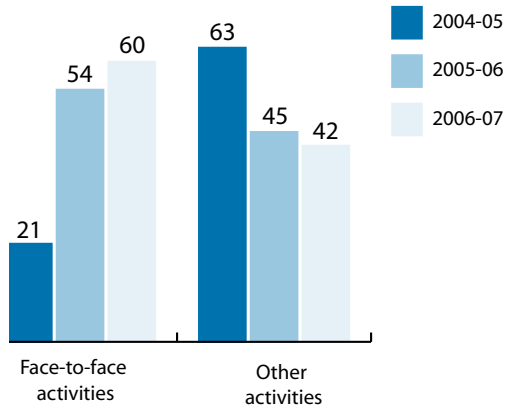
Public involvement activities by level of engagement



The Branch used a range of methods to conduct its public involvement activities.

In 2005–06, the number of face-to-face activities increased from 21 to 54, while the number of other activities, like mail-outs and Web postings, declined from 63 to 45. In 2006–07, the number of face-to-face activities further increased from 54 to 60, while the number of other activities decreased marginally from 45 to 42.

Public involvement activities by method



The methods selected to conduct Branch public involvement activities were chosen based on HPFB's objectives and what level of engagement was required for each issue. As innovative methods for public involvement are developed, changes appear in the methods selected over time, for example, electronic consultation was not available to the Branch in 2004–05.

In 2005–07, the Branch used a variety of methods to consult on many issues (see page 25 for a list of issues).

Methods of public involvement activities

Face-to-face	2004-05	2005-06	2006-07
Consensus conference	0	1	0
Public forum	0	2	0
Symposium	0	1	0
Workshop	12	5	8
Technical consultation	2	14	20
Focus group	3	6	5
Bilateral meeting	0	4	6
Public meeting	2	6	2
Roundtable	2	4	3
Dialogue	0	3	1
Electronic dialogue	0	1	3
Working group	0	2	1
Advisory body	0	3	5
Other	0	2	6
Other			
Mail-out for feedback	24	11	9
Web posting for feedback	32	24	27
Canada Gazette, Part 1	5	4	3
Survey	1	5	0
Other	1	1	3

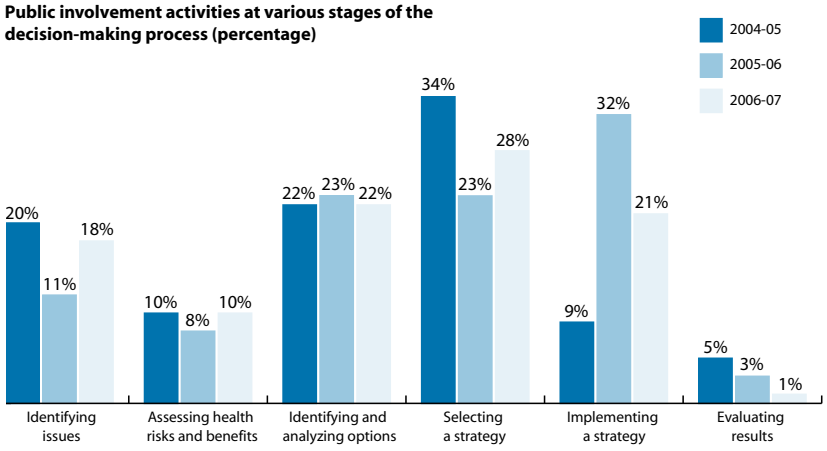
Definitions for each method are provided on page 40.

At what stage in the decision-making process did we consult?

During policy and regulatory development, the Branch involves the public in various stages of its decision-making process—identifying issues, assessing health risks and benefits, identifying and analyzing options, selecting a strategy, implementing the strategy, and evaluating results (see page 7).

In 2005–06 a significant percentage of public involvement activities helped the Branch in implementing a strategy, whereas, in 2006–07, a significant percentage of public involvement activities helped the Branch in selecting a strategy. In 2004–05, a majority of the activities were used in identifying and analyzing options and selecting a strategy.

Public involvement activities at various stages of the decision-making process (percentage)



Who participated in our activities

Objectives in selecting participants

- Involve those affected by the issue
- Involve those who are interested in the issue
- Understand stakeholder concerns
- Achieve a balanced representation
- Obtain expert opinion
- Increase transparency
- Contribute to effective decision and policy making

The Branch generally targets specific groups of participants based on the nature of the topic, the type of input needed, and the level of engagement at which the public is able and willing to contribute. Some issues require highly specialized or technical input, while others benefit most from the perspective of a wide range of participants. In selection processes, the Branch aims to ensure that interested or affected groups are represented in one or more of the six steps of the decision-making framework.

HPFB consultations were held across Canada

The Branch continues to improve its ability to hold public involvement activities in various locations across Canada. Options for participants to connect remotely with the Branch are growing beyond basic teleconferencing, Web postings for feedback, and mail-outs, into innovative technologies such as moderated electronic dialogues or electronic workbooks.

Of the 54 face-to-face activities held in 2005–06, 10 were held in more than one city across Canada:

- Bilaterial meetings on the development of the National Food Safety Strategy and Public Health Outcomes Performance Framework—Winnipeg, Victoria, Regina, Edmundston (New Brunswick), Québec, Halifax, and Moncton
- Focus groups on the draft content for the revised Canada's Food Guide to Healthy Eating—Vancouver, Calgary, Winnipeg, St. John's, Montréal, and Iqaluit
- Focus groups on the usability of the Food Guide Web site mock-ups—Québec and Ottawa
- Stakeholder consultations on the draft content for the revised Canada's Food Guide to Healthy Eating—Ottawa, Burnaby, Winnipeg, Toronto, Moncton, St. John's, Yellowknife, Charlottetown, Montréal, and Regina
- Stakeholder focus groups on the Natural Health Product Directorate's public education and outreach program—Toronto, Montréal, Saskatoon, and Vancouver
- Workshop on animal models for whole food testing for use in the evaluation of safety and nutritional quality of novel foods—Ottawa and Toronto

- Workshops on the Dietary Guidance—St. John's, Halifax, Moncton, Charlottetown, Vancouver, Edmundston (New Brunswick), Regina, Winnipeg, Ottawa, Longueuil, Toronto, and Yellowknife
- Workshops on the Registration and Disclosure of Clinical Trials—Halifax, Ottawa, and Vancouver
- Workshop on measures to help ensure Canadians' continued access to an adequate supply of safe and affordable drugs—Ottawa and Calgary
- Workshops with the food industry on improvement of allergen prevention practices—Ottawa and Toronto

Of the 60 face-to-face activities held in 2006–07, 8 were held in more than one city across Canada:

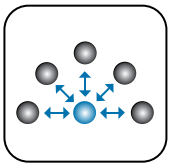
- Animal Biotechnology—Edmonton, Toronto, and Montréal
- Assistant Deputy Minister regional tour on the Blueprint for Renewal—Ottawa, Edmonton, Burnaby, Winnipeg, Toronto, Halifax, and Longueuil
- Awareness and educational sessions for medical device industry on Health Canada's Inspection Program—Moncton, St. John's, and Halifax
- Food Guide Regional meetings (post launch) — Edmonton, Burnaby, Moncton, St. John's, Halifax, and Charlottetown
- Meetings on the Regulatory Framework for Blood and Blood Components—Edmonton, Vancouver, Winnipeg, Toronto, Halifax (including Newfoundland, New Brunswick, and Prince Edward Island stakeholders), Québec, and Regina
- Qualitative research on Food Guide consumer resource—Vancouver, Winnipeg, Toronto, Richibucto, and Montréal
- Qualitative research on layout, comprehensiveness and understanding of content in a draft Food Guide resource for intermediaries—Toronto and Montréal
- Usability testing of Food Guide Web site mock-ups —Toronto and Montréal

Performance stories

In 2005–07 several public involvement activities stood out—the COX-2 and breast implant public forums; the MedEffect consultation; consultations on the registration and disclosure of clinical trial information; the Symposium on Drugs, Food and Natural Health Products Interactions; Blueprint for Renewal; Canada's Food Guide; Consumer Advertising Guidelines for Marketed Health Products, and the Review of Regulated Products: Policy on Public Input.

Each public involvement activity provides the Branch with valuable input and opportunities for learning.

As examples, they demonstrate the diversity of activities conducted by the Branch, the opportunities for learning inherent in our activities, and the impact that public involvement can have on our work. Each highlights a different level of involvement—from gathering information and opinions, to engaging stakeholders in the policy and regulatory decision-making process.



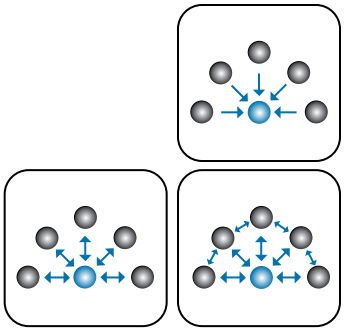
Why a public forum? To promote transparency and broad public awareness of an issue as well as reach a greater number of Canadians.

Public forums: Broadening our perspective in product review

The piloted 2005 public forums on selective COX-2 inhibitor NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) and silicone gel-filled breast implants set a number of precedents for Health Canada, for example, in the disclosure of affiliations and interests of advisory panel members, and the disclosure of some health product submission information. The practical experience in implementing the public forums laid the foundations for a transformative change in the way the Health Products and Food Branch involves the public in its review of decision making.

The public forums were designed to give Canadians multiple ways to learn about the review process and the issues under consideration, as well as the opportunity to provide input. Health Canada's public forum model is distinguished from those of other international regulators by its accessibility, with multiple input mechanisms offered to the public, including a dedicated Web site, and the fact that it adheres more closely to best practices in public involvement processes, for instance by making information available ahead of time and by building in lead time for participants to prepare and participate.

In an independent evaluation of the forums, the majority of informants saw them as a positive step toward increasing openness, transparency, and accountability in the regulatory review process. In terms of accessibility, most public participants agreed that the online mechanism for receiving public input, over and above in-person presentations, made the process more transparent and open, and constituted an innovative and forward-thinking mechanism to solicit broader public input on key health issues.

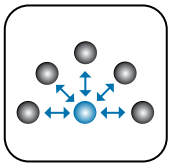


Why interviews, focus groups, and a survey? To allow the development of MedEffect to be a collaborative undertaking, where future users worked with site developers to finalize the site.

MedEffect: Working to improve health product safety

The new Health Canada Web site, MedEffect, is making it easier for patients, consumers, and health care professionals to find the latest safety information on regulated products–like prescription drugs, natural health products, and therapeutic vaccines—marketed for sale or use in Canada.

To ensure that MedEffect is user-friendly, potential users were consulted on the site design before it was launched in August 2005. Health, patient, and consumer associations, individuals, and health care professionals were given an opportunity to look at a prototype of the site and provide their comments to the Health Products and Food Branch. A combination of face-to-face interviews, focus groups, and a Web survey was used to solicit feedback, which was then incorporated in the final MedEffect design.



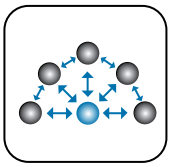
Why an online questionnaire and workshops? To allow for a wide range of stakeholders to discuss issues surrounding the registration and disclosure of clinical trial information.

Access to information on clinical trials: Enhancing transparency

The transparency of clinical trials has become an important issue in Canada and abroad. Patients, prescribers, researchers, and regulators want greater access to information on clinical trials to help them make more informed decisions. Failure to publicly disclose information on clinical trials can reduce efficiency in research, result in the suppression of negative results, prevent prospective participants from becoming involved, and prevent the public from accessing safety and effectiveness information.

In June 2005, the Branch consulted with a wide range of stakeholders to identify the needs and requirements for clinical trial registration. Public input was gathered through an online questionnaire and face-to-face workshops.

Feedback from the consultations provided valuable insight for policy development and led to the establishment of an external working group. In 2006, the working group presented to the Branch options for improving public access to clinical trial information of health products in Canada while respecting the need for patient privacy and commercial confidentiality. The Health Products and Food Branch will consider the results of the public consultations and recommendations before making a final decision on how to proceed with the registration and disclosure of clinical trial information in Canada.

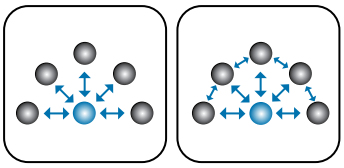


Why a symposium? To promote open time frames for deliberation and discussions on complex issues with international participants.

International symposium to increase awareness of drug, food, and natural health product interactions

Participants from around the world took part in a two-day symposium in Gatineau, Quebec, in February 2006. The goal of the Symposium on Drugs, Food, and Natural Health Products Interactions was to increase awareness of drug, food, and natural health product interactions and to assist the Health Products and Food Branch in developing effective risk management strategies related to the health effects of these interactions.

Organized by the Health Products and Food Branch and the University of Ottawa's Faculty of Science, the event attracted health care professionals, academics, representatives from industry and non-governmental organizations, and government staff. The three scientific sessions focused on risk of interactions, ways to evaluate the potential risks, and surveillance issues. The final session with three panelists dealt with how consumers can avoid the risks of these interactions.



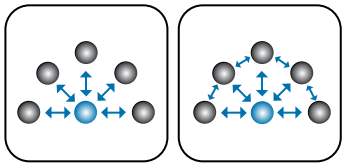
Why an electronic consultation and bilateral meetings? The electronic consultation allowed a range of stakeholders to provide input on policy and program decisions that affect the future direction of HPFB. The bilateral meetings allowed the Branch to meet key stakeholders, listen to their views, share information on the direction of HPFB, and build strategic relationships.

Blueprint for Renewal

In October 2006, the Health Products and Food Branch released its *Blueprint for Renewal* plan, a major initiative aimed at modernizing Canada's regulatory system for health products and food. The Blueprint presented the vision and objectives for the renewal of HPFB's regulatory system, as well as proposed actions for moving forward.

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, where over 300 stakeholders provided their views on the Blueprint's vision and objectives. The Branch received strong support from Canadians on the case for renewal and orientations in the Blueprint. Constructive feedback from the consultations helped inform the development and implementation of the plan and was incorporated into a revised version of the Blueprint. *Blueprint for Renewal II* offers a more comprehensive articulation of the Branch's action plan and how it will concretely move forward to design a regulatory system that will further protect the health and safety of Canadians.

The Branch also held a number of consultations on various Blueprint initiatives key to its renewal. The initiatives included a progressive licensing framework for pharmaceuticals and biologics; a renewed external charging framework that will stabilize the Branch's resources and cover the regulation, licensing, and post-market surveillance of health products; and a regulatory modernization strategy for food and nutrition.



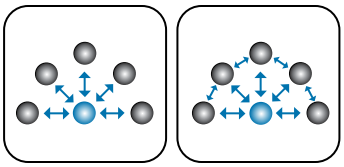
Why an electronic consultation and regional meetings? To allow a broad number of Canadians, many with important regional perspectives on food and nutrition, to take part in the development of the revised Food Guide.

Canada's Food Guide: Providing Canadians with a new tool to help them follow a healthy lifestyle

For 65 years, Canadians have trusted Canada's Food Guide to provide guidance on healthy eating. Canada's first food guide, the Official Food Rules, was introduced to the public in July 1942. Since 1942, the food guide has been transformed many times, including the latest revisions starting in 2005.

More than 7,000 Canadians across the country were consulted, including dietitians, health care professionals, scientists, doctors, and researchers. National consultations were launched in Ottawa in November 2005 and included an online component and a series of regional meetings. The purpose of these meetings was to present some of the key design elements and to provide an opportunity for stakeholders to take part in a dialogue on content issues (presentation of food intake patterns and energy balance), ask questions, and provide feedback on the proposals for Canada's Food Guide. Focus testing with consumers was also done to assess how well the messages were understood. In addition to these consultations, Health Canada received advice and guidance from three expert advisory committees throughout the revision process.

Canada's new Food Guide, released in February 2007, helps Canadians make healthy food choices and describes the amount and type of food recommended for Canadians.



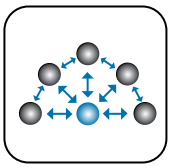
Why a technical consultation and roundtable? To allow stakeholders to voice concerns and propose options for updated guidelines.

Consumer Advertising Guidelines for Marketed Health Products

The Consumer Advertising Guidelines for Marketed Health Products (for non-prescription drugs, including natural health products) replaces the outdated 1990 Consumer Drug Advertising Guidelines. Revised guidelines were developed in collaboration with Advertising Standards Canada and members of the Branch Advertising Working Group. They include a new requirement aimed at providing fair and balanced information on the risks and benefits of non-prescription drugs and natural health products in consumer advertising.

Two rounds of external stakeholder consultation in February 2005 and April-May 2006 resulted in overall support for the draft guidelines; but consensus was not reached on the requirements for the communication of risk information. Consequently, the Health Products and Food Branch invited key stakeholders to Ottawa for a roundtable discussion in June 2006. The event allowed the full range of interested parties to voice concerns and work collaboratively to propose options.

The resulting measures incorporated in the revised guidelines are intended to help Canadians make better informed decisions about their health before purchasing non-prescription products. They are also designed to help advertisers develop advertising messages that meet all the relevant provisions of the *Food and Drugs Act* and Regulations, the *Natural Health Products Regulations,* and other related Health Canada policies and guidelines.



Why an electronic consultation? To provide an opportunity for a broad range of stakeholders to take part in reviewing a draft policy and providing feedback.

HPFB Review of Regulated Products: Policy on Public Input

In June 2005, the Office of Consumer and Public Involvement of the Health Products and Food Branch started developing a policy on public input into the review of regulated products. The Branch developed this policy to promote a more open and transparent system for reviewing the safety and effectiveness of products and food both pre and post market. It recognizes that input from citizens and stakeholders is an important source of evidence in regulatory decision making about benefits and risks.

The Policy sets out standards to follow when the Branch seeks and considers public input. The policy guides the Branch in how to manage information about a regulated product, including

confidential business information, to support informed public participation in its decision-making processes.

In July 2006, as part of its ongoing consultations, HPFB posted the draft Policy and an electronic workbook on Health Canada's Web site. The workbook gave participants information about key policy elements and asked focused questions about them.

To encourage response to the workbook, HPFB sent out 125 e-mails to 18 members of Health Canada's Science Advisory Board and 107 organizations, including officials in industry, health professionals, academics, patients, and consumers. In addition, any visitor to the Health Canada Web site could read the draft policy and complete the workbook questions. In all, 65 people completed the online workbook, 62 in English and 3 in French; results are available online. The input received confirmed HPFB's policy approach and helped to structure the final policy.

Public involvement using ongoing mechanisms

Did you know?

The number of public involvement activities using ongoing mechanisms at HPFB over the last three years.

2004–05: 65 activities

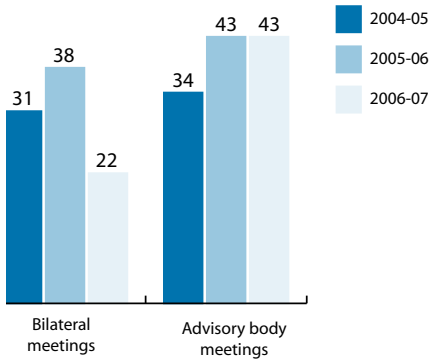
2005–06: 81 activities

2006–07: 65 activities

In 2005–06, the Branch held 38 bilateral meetings and 43 advisory body meetings, and in 2006–07, the Branch held 22 bilateral meetings and 43 advisory body meetings, compared with 31 bilaterals meetings and 34 advisory body meetings in 2004–05.

The Health Products and Food Branch uses a number of ongoing mechanisms to gather input and advice, including bilateral and advisory committee meetings. With external advisors as members, these meetings are a valuable, independent source of information and allow the Branch to communicate its policies and increase the transparency of its decision-making process.

Public involvement activities using ongoing mechanisms



Why we consulted

Regular meetings with various committees and groups ensure that participants are informed on an ongoing basis of the Branch's activities and that their views are heard. While each meeting is held to meet a specific objective, the Branch generally aims to achieve one or more of the following goals:

- to receive medical, technical, scientific, or other expert advice and recommendations on policy development or regulatory issues related to products regulated by the Branch;
- to request advice and guidance on the planning, development, delivery, and evaluation of Branch programs;
- to ensure that the Branch and participants have the same understanding of relevant issues;
- to discuss issues of mutual interest, including regulatory issues, and share information and expertise;
- to solicit advice from a wide variety of stakeholders, including consumers and the public, on major issues and initiatives; and

- to enhance co-operation and collaboration with consulted groups.

Advisory body meetings

Advisory body—Group of representatives from a particular community or with differing interests, who are selected by government bodies to advise, comment, review, or make recommendations for action on any given issue. Terms of reference outline the responsibilities of advisory committees.

The Branch has established a number of standing advisory bodies that provide advice and, in some cases, act as sounding boards to Branch and other Health Canada officials as they carry out their work. These bodies are made up of a wide range of members, and may include health professionals, industry representatives, academics, and patient and consumer representatives. Members are selected, based on their experience and expertise, and according to the purpose of each committee.

In 2005–06, the Branch held 43 meetings with 23 advisory bodies, and in 2006–07, the Branch held 43 meetings with 26 advisory bodies, compared with 34 meetings with 20 advisory bodies in 2004–05 (see page 35 for a list of Branch committees).

Advisory Committee on Management

Did you know?

The Advisory Committee on Management's 19 external members include health professionals, as well as representatives from industry associations, patient and consumer groups, academia, and other levels of government.

The Branch's Advisory Committee on Management met three times in 2005–06 and one time in 2006–07. It provided a forum for senior Health Canada officials and external stakeholders to exchange ideas, opinions, expertise, and advice on a wide range of issues concerning therapeutic products, such as pharmaceuticals (prescription and over-the-counter), medical devices, biologics and genetic therapies (such as vaccines and blood and blood products), radiopharmaceuticals, and natural health products.

Advisory panels or working groups

Advisory panels or working groups are often used to provide ongoing medical, technical, and scientific advice and recommendations on regulatory policies, programs, or issues that arise during the review of health products (see page 36 for a list of advisory panels or working groups).

Members are chosen through a formal nomination process involving a wide range of stakeholders. Panel members are recruited on the basis of their expertise or experience related to the mandate of the advisory body. The Branch also seeks members with a variety of perspectives to ensure that advice is as balanced

and as comprehensive as possible. Broader involvement can be particularly useful in providing alternative perspectives to deal with inherent uncertainty and "imperfect" knowledge, in the scientific context.

Bilateral meetings

Bilateral meeting—A formal meeting usually between government and a stakeholder organization (public or private) to identify, clarify, or increase the knowledge on issues.

The Branch meets with industry and health professional associations to discuss and consult on regulatory issues of mutual interest, share information and expertise, and, when appropriate, discuss responsibilities under the *Food and Drugs Act* and Regulations. Some meetings are held regularly—one to four times a year—while others are conducted as needed to develop relationships or to discuss specific issues. In 2005–06, the Branch held 38 bilateral meetings and, in 2006–07, the Branch held 22 bilateral meetings with various organizations (see page 37 for a list of organizations).

Assistant Deputy Minister stakeholder meetings

In 2006–07, HPFB launched an ADM bilateral meeting program. Through the program, the Assistant Deputy Minister and key Branch officials meet with stakeholders to have open discussions about issues of stakeholder interest. These meetings are initiated by HPFB to help to ensure that stakeholder issues are being addressed at the appropriate level within the Branch, and to provide HPFB with a vehicle to address its issues with stakeholders. Meetings also help to support the Branch's relationships with stakeholders. In 2005–07, the Branch met with 22 stakeholder organizations (see page 38 for a list of organizations).

Annexes

If more than one type of activity was used for an event, the event is listed under each activity.

Public involvement on specific issues

Face-to-face activities

In 2005–07, face-to-face activities were held to obtain feedback on the following issues:

Consensus conference

- Food Allergen Issues and Solutions (2005–06)

Public forum

- Public Forum on Selective Cox-2 Inhibitor NSAIDS (2005–06)
- Silicone Gel-filled Breast Implants (2005–06)

Symposium

- Health Canada International Symposium on Drug, Food and Natural Health Product Interactions (2005–06)

Workshop

- Awareness and educational session for medical device industry on Health Canada's Inspection Program (2006–07)
- CAPRA (Canadian Association of Professional Regulatory Affairs) Workshop – Montréal (2006–07)
- CAPRA (Canadian Association of Professional Regulatory Affairs) Workshop – Toronto (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Grade 9 Biotechnology Teacher's Kit - Ottawa Carleton District School Board Science Professional Development Day (2006–07)
- Information workshop to the food industry on improvement of allergen prevention practices (2005–06)
- MedEffect Web site (2005–06)
- Natural Health Products Research Program - Focused Consultation on Fatty Acids and Essential Fatty Acids (2005–06)
- Progressive Licensing Framework Expert Model Development Meeting (2006–07)
- Progressive Licensing Framework Open Space Workshop (2006–07)

- Registration and Disclosure of Clinical Trials (2005–06)
- Measures to help ensure Canadians' continued access to an adequate supply of safe and affordable drugs (2005–06)
- Training workshop on the preparation of Novel Food Submissions (2006–07)

Technical consultation

- A multi-stakeholder task force, co-chaired by Health Canada and the Heart and Stroke Foundation of Canada, on healthier alternatives and strategies to eliminate or reduce processed trans fat (2005–06)
- Awareness and educational session for medical device industry on Health Canada's Inspection Program (2006–07)
- CAPRA (Canadian Association of Professional Regulatory Affairs) Education Day (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Consultation on Health Canada's revised document on antimicrobial categorization (2006–07)
- Consultation on revised mercury risk management strategy (2006–07)
- Consumer Advertising Guidelines for Marketed Health Products for Non-Prescription Drugs including Natural Health Products (2006–07)
- Draft guidance document: Reconsideration of final decisions issued for human drug submissions (2005–06)
- Draft guidance for industry: Clinical assessment of abuse liability for drugs with central nervous system activity (2006–07)
- Five U.S. generic health claims considered for use in Canada (2006–07)
- Good Guidance Practices Manual for Therapeutic Products (2006–07)
- Grade 9 Biotechnology Teacher's Kit – Ottawa Carleton District School Board Science Professional Development Day (2006–07)
- International Conference on Harmonization (ICH) draft 2 guidance: Q9 Quality Risk Management (2005–06)
- International Conference on Harmonization (ICH) draft 2 guidance: E2B(M) Second Revision of the ICH Guidance on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (2005–06)
- International Conference on Harmonization (ICH) draft 2 guidance: M5 Data Elements and Standards for Drug Dictionaries (2005–06)

- International Conference on Harmonization (ICH) draft 2 guidance: S7B Revised Draft – The Non-clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (2005–06)
- International Conference on Harmonization (ICH) draft 2 guidance: E14 – The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (2005–06)
- International Conference on Harmonization (ICH) draft 2 guidance: Q8 Pharmaceutical Development (2005–06)
- International Conference on Harmonization (ICH) draft 2 guidance: S8 – Immunotoxicity Studies for Human Pharmaceuticals (2005–06)
- Meeting with le Réseau québécois des villes et villages en santé (2006–07)
- Natural Health Products Guidance monographs/document (2005–06)
- Natural Health Products product monographs (2005–06)
- Natural Health Products Research Program (NHPRP) – Focused consultation on fatty acids and essential fatty acids (2005–06)
- Options for improving public access to information on clinical trials of health products in Canada (2006–07)
- Qualitative research on layout, comprehensiveness and understanding of content in a draft Food Guide Resource for Intermediaries (2006–07)
- Qualitative research with triads on Food Guide consumer resource (2006–07)
- Towards a National Regulatory Framework for Whole Blood and Blood Components (2006–07)
- Usability testing of Food Guide Web site mock-ups – draft #2 (2006–07)
- Usability testing of My Food Guide Web site mock-ups – draft #2 (2006–07)
- Use of international reviews in the Biologics and Genetics Therapies Directorate's submission review process (2005–06)
- Veterinary International Cooperation on Harmonization guidelines (2005–06)
- VICH GL 42: International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products Guidelines (2006–07)
- VICH GL 30: International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products Guidelines (2006–07)
- VICH GL 24: International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products Guidelines (2006–07)

Focus group

- Animal Biotechnology (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Draft of the revised Canada's Food Guide to Healthy Eating (2005–06)
- Grade 9 Biotechnology Teacher's Kit – Ottawa Carleton District School Board Science Professional Development Day (2006–07)
- MedEffect – Stakeholder engagement and consultation (internal and external) (2005–06)
- National pharmaceuticals strategy working conference on strengthening the evaluation of real world safety and effectiveness of drug products (2005–06)
- Qualitative research on layout, comprehensiveness, and understanding of content in a draft Food Guide Resource for Intermediaries (2006–07)
- Qualitative research with triads on the Food Guides Consumer Resource (2006–07)
- Qualitative study on the Natural Health Products Directorate's public education and outreach program with stakeholders (2005–06)
- Usability of MedEffect Web site and the adverse reaction reporting form (2005–06)
- Usability testing of Food Guide Web site mock-ups (2005–06)

Bilateral meeting

- Ayurvedic stakeholder information session and outreach (2005–06)
- Blueprint for Renewal bilateral meetings (2006–07)
- Bulk Natural Health Product Policy (2006–07)
- Consultation on revised mercury risk management strategy (2006–07)
- MedEffect - Stakeholder engagement and consultation (internal and external) (2005–06)
- MedEffect Web site (2005–06)
- Meeting with le Réseau québécois des villes et villages en santé (2006–07)
- Meeting with provincial and territorial governments on the development of a national strategy on public health outcomes for food safety and nutritional quality (2005–06)
- Nuclear Medicine Alliance/Canadian Society of Nuclear Medicine (2006–07)
- Special Access Program (SAP) Comprehensive Review, Guidance Document, Policy/ Regulatory Review (2006–07)

Public meeting

- Ayurvedic stakeholder information session and outreach (2005–06)
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition, and quality (2006–07)
- Food Guide Regional Meetings – post launch (2006–07)
- Health Canada International Symposium on Drug, Food, and Natural Health Product Interactions (2005–06)
- MedEffect Web site (2005–06)
- Stakeholder consultation on draft content for the revised Canada's Food Guide to Healthy Eating (2005–06)
- Stakeholder meeting on the reprocessing of single-use medical devices (2005–06)
- Stakeholder regional meetings on draft content for the revised Canada's Food Guide to Healthy Eating (2005–06)

Roundtable

- Blueprint for Renewal Assistant Deputy Minister Regional Tour (2006–07)
- Consultation on revised mercury risk management strategy (2006–07)
- Consultation on the development of environmental assessment regulations for substances contained in products regulated under the Food and Drug Act (2005–06)
- Consumer Advertising Guidelines for Marketed Health Products for Non-Prescription Drugs including Natural Health Products (2006–07)
- MedEffect Web site (2005–06)
- Natural Health Products Research Program – Focused Consultation on Fatty Acids and Essential Fatty Acids (2005–06)
- Measures to help ensure Canadians' continued access to an adequate supply of safe and affordable drugs (2005–06)

Dialogue

- MedEffect – Stakeholder engagement and consultation (internal and external) (2005–06)
- Nuclear Medicine Alliance/Canadian Society of Nuclear Medicine (2006–07)
- Stakeholder consultation on draft content for the revised Canada's Food Guide to Healthy Eating (2005–06)
- Stakeholder Regional Meetings on draft content for the revised Canada's Food Guide to Healthy Eating (2005–06)

Electronic dialogue

- Blueprint for Renewal electronic consultation (2006–07)
- Natural Health Products Regulatory Review (2006–07)
- HPFB Review of Regulated Products: Policy on Public Input (2005–07)

Working group

- MedEffect - Stakeholder engagement and consultation (internal and external) (2005–06)
- MedEffect Web site (2005–06)
- Environmental Assessment Working Group (2006–07)

Advisory bodies

- A multi-stakeholder task force, co-chaired by Health Canada and Heart and Stroke Foundation of Canada, on healthier alternatives and strategies to eliminate or reduce processed trans fat (2005–06)
- Bulk Natural Health Product Policy (2006–07)
- Dispute Avoidance and Resolution Policy for Natural Health Products (2006–07)
- Expert Advisory Committee on Cells, Tissues, and Organ Regulation (2006–07)
- MedEffect Web site (2005–06)
- Natural Health Products monographs (2006–07)
- Natural Health Product Regulations guidance documents (2006–07)
- Reprocessing of Single-Use Medical Devices (2005–06)

Other types of face-to-face activities

- Blueprint for Renewal electronic consultation (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Consumer Advertising Guidelines for Marketed Health Products for Non-Prescription Drugs including Natural Health Products (2006–07)
- Executive interviews with intermediaries who promote healthy eating in multicultural communities (2005–06)
- Expert Advisory Committee on Cells, Tissues, and Organ Regulation (2006–07)
- Food Guide Regional Meetings – post launch (2006–07)
- Health Canada booth at the BioMedex Industry Trade Show (2006–07)
- Partnership with the University of Ottawa for the Health Canada International Symposium on Drug, Food, and Natural Health Product Interactions (2005–06)

Other types of activities

Mail-outs for feedback

- Animal Livestock Cloning for Food Use (2005–06)
- Bulk Natural Health Product Policy (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Consumer Advertising Guidelines for Marketed Health Products for Non-Prescription Drugs including Natural Health Products (2006–07)
- Development of Canadian input into elaboration of world-wide Codex standards for food safety, nutrition, and quality (2006–07)
- Draft guidance for industry: Impurities in Existing Drug Substances and Products (2005–06)
- Draft guidance for industry: Changes in Product Colour or Markings (2005–06)
- Draft guidance for industry: Product Monographs of Non-Contraceptive Estrogen/Progestin-containing Products (2005–06)
- Homeopathic Medicine Definition (2006–07)
- Interim compounding material policy for Natural Health Products (2005–06)
- Interim raw material policy for Natural Health Products (2005–06)
- Joint Health Canada/European Union Guidance on Pharmaceutical Quality of Inhalation and Nasal Products (2005–06)
- Labeling of Unpasteurized/Pasteurized Fruit Juice/Cider (2005–06)
- Mandatory Reporting of Adverse Reactions by Health Professionals (2005–06)
- Modifications to Health Canada's Unpasteurized Juice Policy (2006–07)
- Natural Health Products Monographs (2006–07)
- Pharmacogenomics Guidance (2005–06)
- Project 743 – Non-medicinal ingredients: Requirements for listing on product labels (2006–07)
- Raw Milk Cheese Code of Practice (2006–07)
- Silicone Gel-filled Breast Implants (2005–06)

Web postings for feedback

- Amendment to the Food and Drug Regulations – Addition of two medicinal ingredients to Schedule F (2005–06)

- Audit Program Frequently Asked Questions document (2006–07)
- Blueprint for Renewal electronic consultation (2006–07)
- Clinical Trial Application templates (2006–07)
- Clinical Trials Regulatory Framework Review – national consultations (2006–07)
- Consumer Advertising Guidelines for Marketed Health Products for Non-Prescription Drugs including Natural Health Products (2006–07)
- Development of Canadian input into elaboration of world-wide Codex standards for food safety, nutrition, and quality (2006–07)
- Draft guidance document: Reconsideration of Final Decisions Issued for Human Drug Submissions (2005–06)
- Draft guidance for industry: Impurities in Existing Drug Substances and Products (2005–06)
- Draft guidance for industry: Basic Product Monograph Information for Non-steroidal Anti-Inflammatory Drugs (2005–06)
- Draft guidance for industry: Changes in Product Colour or Markings (2005–06)
- Draft guidance for industry: Clinical Assessment of Abuse Liability for Drugs with Central Nervous System Activity (2006–07)
- Draft guidance for industry: Guide for the Analysis and Review of QT/QTc Interval Data (2006–07)
- Draft guidance for industry: Instructions to be included with reusable medical devices (2006–07)
- Draft guidance for industry: Patented Medicines (Notice of Compliance Regulations) (2006–07)
- Draft guidance for industry: Product Monographs of Non-Contraceptive Estrogen/Progestin-containing Products (2005–06)
- Draft guidance for Industry: QT/QTc Interval Prolongation: Guidance for Product Monograph Content (2006–07)
- Draft guidance for Industry: Reporting Adverse Reactions to Marketed Health Products (2005–06)
- Draft guidelines: Good Manufacturing Practices Requirements for Positron-Emitting Radio-pharmaceuticals (2005–06)
- Draft: Notice of Compliance (NOC) Changes Project (2006–07)
- Five U.S. generic health claims considered for use in Canada (2006–07)

- Good Guidance Practices Manual for Therapeutic Products (2006–07)
- Good Manufacturing Practices (GMP) for Medical Gases (GUI-0031) (2006–07)
- Good Manufacturing Practices (GMP) Guidelines (GUI-0001) (2006–07)
- Health Canada International Symposium on Drug, Food, and Natural Health Product Interactions (2005–06)
- HPFB Review of Regulated Products: Policy on Public Input (2006–07)
- International Conference on Harmonization (ICH) Guidance E15: Pharmacogenomics (Step 2) (2006–07)
- International Conference on Harmonization (ICH) Guidance Q4B: Regulatory acceptance of analytical procedures and/or acceptance criteria and Annex 1, residue on ignition/sulphated ash (2006–07)
- Inspection Strategy for the Canadian Access to Medicines Regime (POL-0055) (2006–07)
- Joint Health Canada/European Union Guidance on Pharmaceutical Quality of Inhalation and Nasal Products (2005–06)
- Labelling of Unpasteurized/Pasteurized Fruit Juice/Cider (2005–06)
- Letter to Quality Systems Auditing Organizations (2006–07)
- Mandatory Reporting of Adverse Reactions by Health Professionals (2005–06)
- Manufacturing and Compounding Drug Products in Canada (POL-0051) (2006–07)
- MedEffect – Stakeholder engagement and consultation (internal and external) (2005–06)
- MedEffect Web site (2005–06)
- Modifications to Health Canada's Unpasteurized Juice Policy (2006–07)
- Pharmacogenomics Guidance (2005–06)
- Process Validation Guidelines for Terminal Sterilization Process for Pharmaceutical Products (GUI-0074) (2006–07)
- Project 743 – Non-medicinal ingredients: Requirements for listing on product labels (2006–07)
- Project 1330 – Addition of sibutramine to Schedule F (2005–06)
- Project 1370 – Addition of nicotine lozenge to Schedule F (2005–06)
- Project 1405 – Addition of seven medicinal ingredients to Schedule F (2005–06)
- Project 1439 – Addition of five medicinal ingredients to Schedule F (2005–06)
- Project 1445 – Addition of alefacept to Schedule F (2005–06)

- Project 1448 – Addition of danofloxacin to Schedule F (2005–06)
- Project 1451 – Additional of medicinal ingredients to Schedule F (2005–06)
- Project 1452 – Addition of medicinal ingredients to Schedule F (2005–06)
- Project 1476 – Addition of medicinal ingredients to Schedule F (2005–06)
- Public Forum on Silicone Gel-filled Breast Implants (2005–06)
- Release of revised Form IV and Form V, pertaining to the Patented Medicines (Notice of Compliance) Regulations (2006–07)

Publications in Canada Gazette Part 1

- Amendments to Division 2 of the Food and Drug Regulations (2006–07)
- Project 1184 – Modafinil (2005–06)
- Project 1385 – Schedule F exemptions for Vitamin K (2005–06)
- Project 1421 – Removal of clobetasone from Schedule F (2005–06)
- Project 1474 – Schedule F (2005–06)
- Project 1482 – Data protection (2006–07)
- Project 1510 – Schedule F exemption (2006–07)

Survey

- MedEffect Web site (2005–06)
- National Pharmaceuticals Strategy (NPS) working conference on strengthening the evaluation of real-world safety and effectiveness of drug products (2005–06)
- On-line and phone survey of stakeholders consultation on draft content for the revised Canada's Food Guide to Healthy Eating (2005–06)
- Qualitative study on public education and outreach program with natural health products stakeholders (2005–06)
- Registration and Disclosure of Clinical Trials (2005–06)

Other

- Food Guide Regional Meetings – Post Launch (2006–07)
- Report and feedback on the Options Analysis Paper – An environmental assessment regime for the new substances in products regulated under the Food and Drugs Act (2005–06)
- Usability testing of Food Guide Web site mock-ups – draft #2 (2006–07)
- Usability testing of My Food Guide Web site mock-ups – draft #2 (2006–07)

Ongoing public involvement

Scientific advisory bodies

- **Attention Deficit/Hyperactivity Disorder.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–06)
- **Bill C9.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes and suggests issue/options to be explored. (2006–07)
- **Medical Devices Used in the Cardiovascular System.** Provides ongoing advice on medical devices used in the cardiovascular system. (2005–07)
- **Metabolic and Endocrine Therapies.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–07)
- **Musculoskeletal Therapies.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005-07)
- **Neurological Therapies.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–07)
- **Oncology subgroup for pharmaceutical submission issues.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–06)
- **Pediatrics.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–07)
- **Respiratory and Allergy Technologies.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–07)

Expert advisory bodies

- **Advisory Committee on Management.** Provides the Assistant Deputy Minister and the Branch Executive Committee of HPFB with informed feedback from stakeholders on issues pertaining to HPFB planning, programs, and management. (2005–07)
- **Antimicrobial Resistance Risk Assessment.** Provides expert advice on available risk assessments, methodology, and applications to evaluate the health risks of specific antimicrobial agents and to make evidence-based risk-management decisions on the animal-use of antimicrobial agents, particularly those used in food-producing animals. (2005–07)

- **Blood Regulations.** Provides the Biologics and Genetic Therapies Division with advice on medical and scientific issues relevant to deferral responsibilities within the national blood system. (2005–07)
- **Cells, Tissues, and Organs Regulations.** Provides the Biologics and Genetic Therapies Directorate with advice on developing and implementing proposed regulations. (2005–07)
- **Dietary Reference Intakes.** Provides advice and recommendations on how best to apply the Dietary Reference Intakes. (2005–06)
- **Food Guide Advisory Committee.** Provides advice and guidance on revising Canada's Food Guide to Healthy Eating and supporting materials. (2005–07)

Scientific advisory panels

Scientific advisory panels (SAPs) provide medical, technical, and scientific advice and recommendations on a variety of issues, including the safety and efficacy of some of the products regulated by Health Canada. Panel members are appointed by Health Canada.

- **Expert Advisory Panel on Aquaculture Veterinary Drugs.** Provides input and advice on the decision-making process used by the Veterinary Drugs Directorate to establish interim maximum residue limits and withdrawal periods for needed aquaculture veterinary drugs. (2006–07)
- **Fentanyl BE Reuirements.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2006–07)
- **Hepatoxicity.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2006–07)
- **Human Reproductive Therapies.** Provides medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2005–06)
- **Isotretinoin Expert Working Group.** Provides ongoing medical, technical, and scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. Issues and options explored by committee/panel. (2005–07)
- **Reprocessing of Medical Devices.** Provides technical and scientific advice on current and emerging issues for reprocessing of medical devices. (2005–07)

Other panels and working groups

- **Clinical Trials External Working Group.** Provides ongoing medical, technical, scientific advice and recommendations on regulatory issues for drugs in specific therapeutic areas or classes. (2006–07)
- **Extra-Label Drug Use Advisory Committee.** Provides a forum for advice from the

stakeholder community on issues related to policy development on extra-label drug use in animals. (2005–07)

- **Management Advisory Committee for the Natural Health Products Directorate.** Provides advice to management on the administration of the natural health products program. (2005–07)
- **Natural Health Products Directorate Expert Advisory Council.** Provides expert advice on issues relating to the safety, quality, and efficacy of natural health products. (2005–07)
- **Network on Healthy Eating.** Provides collaboration, co-operation, and coordination to support healthy eating and nutrition in Canada. (2005–07)
- **Special Access Program Working Group.** Provides input on the issue analysis summary, program guidance document, and discussion paper following a study of the ethical context of SAP's mandate and activities. (2006–07)
- **Task Force on Personal Importation of Veterinary Drugs.** Provides advice on the importing of veterinary drugs for personal use situations and develops recommendations that address the issues raised. (2006–07)
- **Veterinary Drugs Directorate Minor Uses/Minor Species Working Group.** Provides advice on the lack of approved drugs for minor uses/minor species, particularly in food-producing animals. The intention is that this working group will become an advisory committee. (2005–07)
- **Veterinary Drugs Directorate Stakeholder Committee.** Provides a forum for obtaining input from the stakeholder community on key issues that are the responsibility of the Veterinary Drugs Directorate. (2005–07)
- **Voluntary Statement of Information for Public Involvement Evaluation Working Group.** Provides guidance to the Office of Consumer and Public Involvement on the final report of evaluation findings. (2006–07)

Bilateral meetings

Bilateral meetings are used regularly by HPFB to meet with stakeholder groups to discuss regulatory issues. In 2005–07, the Branch met with the following organizations:

- BIOTECanada
- Canada's Medical Device Technology Companies
- Canada's Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Association for Pharmacy Distribution Management
- Canadian Consumer Specialty Products Association
- Canadian Cosmetic, Toiletry and Fragrance Association

- Canadian Food Inspection Agency–Food Industry Multi-Stakeholder Committee
- Canadian Generic Pharmaceutical Association
- Canadian Homeopathic Pharmaceutical Association
- Canadian Medical Association
- Canadian Pharmacists Association
- Canadian Society of Hospital Pharmacists
- Compressed Gas Association
- Direct Sellers Association
- Groupement provincial de l'industrie du médicament
- MEDEC: Canada's Medical Device Technology Companies
- National Association of Pharmacy Regulatory Authorities
- NDMAC
- Nuclear Medicine Alliance/Canadian Society of Nuclear Medicine
- Advertising Standards Canada

Assistant Deputy Minister stakeholder meetings

Assistant Deputy Minister meetings are stakeholder meetings to discuss stakeholder issues and to take a proactive approach to stakeholder relationship-building. In 2005-07, the ADM met with the following stakeholders:

- Allergan, Inc.
- Altana Pharma Inc.
- Apotex Incorporated
- Best Medicines Coalition
- BIOTECanada
- Bristol Myers Squibb
- Canadian Agri-Food Policy Institute
- Canadian Association of Chain Drug Stores
- Canadian Consumer Specialty Products Association
- Canadian Council for Donation and Transplantation
- Canadian Generic Pharmaceutical Association

- Canadian Health Food Association
- Canadian Pharmacists Association
- Canadian Public Health Association
- Canada's Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Cosmetics, Toiletry and Fragrance Association
- Federation of Medical Regulatory Authorities of Canada
- MEDEC: Canada's Medical Device Technology Companies
- National Association of Pharmacy Regulatory Authorities
- Pfizer Canada Inc.
- Wellington Strategy of Canada and Croplife Canada
- Women and Health Protection

Glossary

Advisory body — Group of representatives from a particular community or with differing interests, who are selected by government bodies to advise, comment, review, or make recommendations for action on any given issue. Terms of reference outline the responsibilities of advisory bodies.

Bilateral meeting — Formal meeting usually between government and a stakeholder organization (public or private), mainly used to identify or clarify issues and increase the knowledge base on the issues. These meetings are part of a public involvement plan or strategy and exclude intermittent (meaning periodic or everyday) business meetings with stakeholders.

Consensus conference — A consensus conference, or a citizens' conference, is where an unaffiliated group of individual citizens becomes informed about an issue and formulates a set of recommendations for policymakers and the public. Similar to a "citizens' jury" approach, the main aim of the project is to influence the policy-making process by opening up a dialogue between the public, experts, and government.

Consumer groups — Users or purchasers of the products or services of the Branch or Health Canada who are a segment of the public.

Dialogue — Structured and usually moderated process to discuss and deliberate on issues. This public involvement method enables participants with differing values and priorities to interact, exercise influence, and build a common understanding of the problems and opportunities. Types of dialogue include e-dialogues, appreciative inquiries, and deliberative dialogues.

Focus group — Structured process where specifically selected individuals are brought together to provide reactions to a specific topic, policy, project, or issue.

Health professional associations — Organizations representing the interests of physicians, nurses, pharmacists, dentists, hospital administrators, natural health practitioners, alternate medicine practitioners, and other types of health professionals, are a segment of the public.

Mail-out for feedback — Distribution of feedback letters or information kits to stakeholders or interested parties to provide knowledge of a subject and seek input or comments (including e-mail notification).

Patient groups Individuals who require or who are under medical care and are a segment of the public. A patient may also be a consumer; however, not all consumers are patients.

Public Forum A public forum is a meeting where the public is invited to contribute input to a working group or advisory panel. A public forum broadens the discussion relating to a specific activity or project to include input from a wider audience and provides additional information and a broader perspective to panel or committee members. The input is an important element of the information considered in order to make a decision on an issue.

Public Defined broadly and inclusively to cover all the individuals or groups who may be interested in or affected by the decision-making body. The definition does not require the certainty that any individual or group has such an interest, just that they may have. The public therefore includes consumers, patients, professionals, academia, industry, and the groups that represent them.

Public meeting Meeting open to stakeholders and the public where the government makes a formal presentation on a policy, project, or issue and the public is given the opportunity to react with questions and comments.

Round table Meeting where a group of people gather to discuss specific issues on which they have a common interest or expertise. The concept of a "round" table comes simply from the fact that no one is the "head" of the table.

Stakeholders Individuals, groups, or organizations that are affected by or interested in an issue or policy. Stakeholders, interested parties, and affected parties are segments of the public consisting of those that the Branch knows are interested in the specific subject matter, based primarily on previous experience with them. The Branch interacts regularly with different types of stakeholders, such as health professionals, academia, industry, patients, and others.

Survey Method of primary data collection based on communication with a representative sample of individuals using different information-gathering methods, such as mail-out questionnaires, in-person or telephone interviews, and e-mail and Internet-based methods.

Technical consultation Consultation in which selected participants with scientific or technical expertise are invited to provide input and feedback on the development of government guidelines, research programs, and so on (including expert working groups).

Web posting Posting of an invitation to provide input on a question, issue, or document on the World Wide Web (including a call for briefs or proposals).

Workshop Interactive meeting in which participants expect to be involved in group discussion on one or more theme areas. The intent is usually to identify problems and expectations or to recommend solutions.

Working group Group of representatives from a particular community or with differing interests who are selected by government bodies to work together on a specific activity or project, toward a specific outcome. Working groups can work at strategic or operational levels.