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Health Policy Research Bulletin

Regulatory Modernization

Health Policy Research Bulletin

In This Issue

Regulatory Modernization:

Reshaping Canada's Health and Safety Systems for Food, Health and Consumer Products

Canada's regulatory systems for food, health and consumer products have served Canadians well over the years. However, recent trends such as advances in science and technology, globalization and changing consumer demands are driving the need for regulatory modernization in Canada and around the world.

In light of these trends, Health Canada is working with stakeholders to update its regulatory systems. By drawing on experiences from across the Department, this issue of the *Health Policy Research Bulletin* explores the variety of ways that pressures are being addressed and examines the range of evidence that is informing the modernization of regulatory instruments and mechanisms. In particular, this issue:

- examines the history and limitations of the existing regulatory frameworks and identifies the trends and pressures for change
- explores some of the regulatory changes underway, including those related to prescription drugs, food safety and chemicals management
- discusses the clinical trial regulations, updated in 2001, and presents the results of an evaluative study of their impacts
- looks at the role of international regulatory cooperation in safeguarding health and safety standards and in streamlining regulatory processes
- highlights the importance of regulatory foresight and examines some of the associated methodologies and challenges

Finally, the issue discusses some of the "lessons learned" by Health Canada as it reflects on its experiences and works to continuously improve how it carries out its regulatory mandate.

Canada

For Further Reading

Access to Therapeutic Products: The Regulatory Process in Canada **(Health Canada, 2006):**
http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php

Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food **(Health Canada, 2007):**
http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/blueprint-plan_II-eng.php

Cabinet Directive on Streamlining Regulation **(2007):**
http://www.tbs-sct.gc.ca/ri-qr/directive/directive00-eng.asp

Consumer Product Safety—Acts and Regulations:
http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/index-eng.php

Fact Sheet for Consumers on the Proposed *Canada Consumer Product Safety Act* (Bill C-6):
http://www.hc-sc.gc.ca/cps-spc/pubs/cons/bill_c6-loi-eng.php

Food and Consumer Safety Action Plan (Healthy Canadians website):
http://healthycanadians.ca/pr-rp/action-plan_e.html

Health Canada Report on Plans and Priorities:
http://www.tbs-sct.gc.ca/rpp/2009-2010/inst/shc/shc00-eng.asp

Health Canada's Regulatory Modernization Strategy for Food and Nutrition (RMSFN) **(Health Canada, 2008):**
http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/consultation/rm_strat_mr-eng.pdf

Policy Research Initiative, Regulatory Strategy:
http://www.policyresearch.gc.ca/page.asp?pagenm=2009-0014_01

Strengthening and Modernizing Canada's Safety System for Food, Health and Consumer Products **(Health Canada, 2009):**
http://www.healthycanadians.ca/pr-rp/dpaper-papier_e.html

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Regulatory Modernization: Rethinking Our Health and Safety Systems

In this issue, Nancy Hamilton, Managing Editor of the Health Policy Research Bulletin, *speaks with* **Michael Vandergrift** *(MV), Director General, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada;* **Hélène Quesnel** *(HQ), Director General, Legislative and Regulatory Policy Directorate, Strategic Policy Branch, Health Canada; and* **Hilary Geller** *(HG), Director General, Policy and Planning Directorate, Healthy Environments and Consumer Safety Branch, Health Canada.*

Q ***This issue of the Bulletin focuses on regulatory modernization, particularly as it relates to our safety systems for food, health and consumer products. What do we mean by "regulatory modernization" and why is it a priority at this time?***

HQ: Many of our legislative instruments were developed decades ago and do not take into account the changes in our external environments that have occurred since then. Regulatory modernization stems from the recognition that as our circumstances evolve, so too must our interventions keep pace to protect and maintain the health of Canadians.

MV: Speaking from the perspective of health products and food, regulatory modernization encompasses efforts to update an outdated regulatory system that is based on legislation—the *Food and Drugs Act* (FDA)—established in the 1920s. Although the Act was amended in the early 1960s in response to the thalidomide tragedy, it has remained focused on the pre-market approval of drugs. In proposing to modernize the FDA and its regulations, we are considering the risks and benefits throughout a drug's entire life cycle and ways to strengthen the safety assessments after a drug has been approved for sale and when it is on the market.

HG: It's important to note that our efforts to modernize didn't begin yesterday. In the early 1990s we recognized that our regulatory systems needed more than "tweaking"—we needed a substantive rethink of our overall approach.

Q ***What are some of the key drivers behind regulatory modernization?***

HG: A key driver is the availability of new types of products, such as organs, blood, tissues and assisted human reproductive techniques that did not exist 50 years ago and so were not covered in legislation. Advances in science have also meant that many legislative instruments have become outdated. As the science has evolved, so has our knowledge about the risks to health and the points at which interventions are needed to protect Canadians. This has allowed us to develop modern approaches, such as those reflected in the *Chemicals Management Plan* (see article on page 32).

HQ: Another driver is the global nature of our economy. Our regulations can no longer be developed just for Canada, as the products we regulate and the industries affected are multinational. For Canada to be a vital force in the global economy, our products have to compete on an equal footing. Current economic stressors are also unprecedented. So, more than ever, regulations must achieve the highest level of protection while minimizing the burden on industry.

MV: Important demographic shifts are also taking place and are affecting consumer demand for new products and therapies (see article on page 12). Additionally, the views of Canadians on the role of government in regulation have changed, including the value that regulation provides in advancing public policy goals.

HG: Another key issue concerns the role of government in keeping its citizens safe. At the core of the debate, not only in Canada, but also in countries around the world, are such questions as: "What is the role of government, of industry and of consumers?" Government can't do it all. Industries have a responsibility to be aware of the products they're selling and to take preventive action for any potential harm that they might cause. There are also public expectations and questions about what consumers want. For example, as a society, what is our attitude toward risk?

Q What are some of the challenges facing Health Canada as a modern regulator? Are they common to regulators internationally?

MV: Regulators have to balance a number of challenges. While consumers are demanding a greater role in regulation making, they also want timely access to products; and so they're putting pressure on regulators to make decisions more efficiently. The growing number of products brought about by advances in science and technology is also adding to the pressure for safety and efficiency.

HQ: Today's regulators operate in a global trade environment where products manufactured in one country may be made from parts or ingredients produced in other countries, not all of which have similar safety standards. This has led to demands for more streamlined, internationally consistent and recognized regulations, which will achieve stronger protection and prevention, but which will also foster innovation and competitiveness (see article on page 37).

MV: These challenges are common internationally and various countries are taking steps to modernize their regulatory programs. For example, the European Medicines Agency has recently launched a roadmap for 2010 which is similar in many ways to Health Canada's modernization initiatives, such as the *Blueprint for Renewal*. The Blueprint is focusing on modernizing outdated regulations and tools for new product categories, building stronger compliance and enforcement capacity, and strengthening post-market surveillance systems.

Q Health Canada regulates a spectrum of food, health and consumer products. Are there common approaches to addressing the regulatory challenges across product lines?

HG: Canada's *Food and Consumer Safety Action Plan*, which was announced by the Prime Minister in December 2007, has been particularly helpful in addressing the challenges that are common across the different product lines.

The Action Plan organizes the initiatives to modernize Canada's safety system around a conceptual framework that has three pillars. First, there's **active prevention**—this is about building safety considerations into the development and use of products so that we can prevent as many incidents as possible. Then, there's **targeted oversight**, which allows regulators to keep a closer watch on high-risk products by requiring safety tests throughout the product's life cycle. Finally, there's **rapid response**, which provides government with the power to respond rapidly to remove unsafe products from the marketplace.

HQ: We also have a new *Cabinet Directive on Streamlining Regulation* that reinforces key principles, such as ensuring that regulations achieve their intended outcomes (see article on page 9). The Directive also introduces two new requirements—for more rigorous cost-benefit analysis and for demonstrating that every regulation has a net benefit for society. How we hold ourselves accountable and how we engage with those affected by what we do is changing and becoming much more transparent.

Also common across regulatory systems is the heightened importance of working with industry, particularly in light of recent economic challenges. Regulations must be made in ways that do not place undue burden on industry and that harmonize to the extent possible with other jurisdictions, while still allowing businesses to innovate and remain competitive. Achieving a balance between meeting public health and safety objectives and supporting the economy can be challenging and requires longer term, forward thinking policy making, as seen with the Action Plan.

Q In modernizing Canada's safety system, what instruments does Health Canada have at its disposal? How do regulations fit into the mix?

HG: As a government regulator, Health Canada has a range of instruments for achieving its public policy objectives, from laws and regulations, economic incentives and penalties, to forms of self-regulation and voluntary action. Regulatory modernization can involve changing the mix of instruments used, amending existing regulations, or rethinking the laws or Acts upon which regulations are based. For example, the proposed *Canada Consumer*

Product Safety Act, if enacted, will address many of the deficiencies of the existing *Hazardous Products Act*.

HQ: Acts and regulations are both instruments of law. In essence, a law establishes the rules of behaviour of all citizens within the country. Regulations are secondary laws that set out in more detail how the broader rules (laws) are to be interpreted and applied (see article on page 7). Government's role is to ensure that the regulations are explained in a way that they can be understood and complied with, and that the outcomes meet the original objectives of the law.

MV: Regulations are usually combined with other instruments, such as policies and guidelines. For instance, the *Food and Drug Regulations* set out rules for the safety and nutritional quality of food, while policies and guidelines help stakeholders interpret the regulations and understand their requirements.

How do you decide which instruments to use?

HQ: The three pillars in the Action Plan provide direction on using the right instrument or set of instruments for the particular circumstance. For example, in order to prevent problems, information about products is provided to consumers, as well as to industry (with respect to the standards they must follow and how to comply). For targeted oversight, tools such as inspections and mandatory reporting protocols are available. Then, there are compliance and enforcement instruments that provide the basis for action when problems arise. These can range from educational campaigns and guidelines that foster voluntary compliance to instruments that have the force of law.

HG: Modern compliance approaches involve a suite of instruments—from the least to the most intrusive—that are used in different situations depending on the severity of the risk. An example of this is the *Administrative Monitoring Penalty Scheme* (AMPS), which we will be introducing if the proposed *Canada Consumer Product Safety Act* comes into force. As criminal prosecution is often inappropriate and time consuming, the AMPS provides for a range of penalties (from very light fines to those in the thousands of dollars) between inaction and criminal prosecution. In general, the goal is to use the least intrusive instrument(s) that will bring about the desired effect.

What type of evidence is informing Health Canada's modernizing activities?

HG: A variety of evidence supports the modernization process. There's evidence that a problem exists (such as deaths, near-misses and consumer adverse reactions to products, both in Canada and internationally). Then there's evidence to tell us how to deal with it. At the end of the day, this information is only important when someone decides to act on the problem. So, the really useful question is, "What type of evidence triggers action?"

Sometimes, even in the presence of scientific evidence, it takes a marketplace event to trigger action. For example, during the summer of 2007, there were problems related to products with high lead levels. Despite previous attempts to modernize the *Hazardous Products Act*, it took public outcry over the paint on Thomas the Tank Engine™ before reform of the 40-year-old Act would begin. The bottom line is there's not a simple evidentiary line; it's complicated, with numerous sources of evidence that come into play.

We also look at the international situation, including what our major trading partners are doing and why, as well as the external environment, the overarching approach of government, what the Supreme Court is saying, and what the public thinks. There's always a role for hard statistics and econometric modelling-type evidence. Generally speaking, the type of evidence we use is similar to that used 50 years ago, but with a stronger emphasis on public and stakeholder opinion.

MV: In the area of health products and food, we have held a number of major consultations with our stakeholders, including patient safety groups, industry, consumers and our expert advisory committees. The volume of input is challenging us to apply comprehensive methods to analyze this information so that it can be more effectively utilized in the decision-making process (see article on page 44).

HQ: Feedback from industry is also important, especially to inform us when the regulations are not working well. We also conduct our own analyses of the potential impacts that new laws and regulations might have on the sectors we regulate. We receive input and advice from advocacy groups who take the pulse of their membership and represent the interests of specific sectors. All of these, including Parliamentary Committee reports, are important sources that broaden our understanding

of what needs to be considered and which instruments should be used. They also help us to broaden our focus to consider not only the health and safety outcomes but the ethical, social, economic and legal impacts of regulatory action.

What have been some of the major regulatory changes (accomplishments) to date?

MV: I would say that the major accomplishments are threefold. First, we continue to take effective regulatory actions to improve the health and safety of Canadians, such as the approval of the H1N1 vaccine. We are also using new technology to enhance regulatory efficiencies, for example, using an electronic review process for natural health products (NHP) made possible by the new "NHP-online" site. Second, we are modernizing our regulatory frameworks. For example, we've introduced a new framework for the regulation of cells, tissues and organs, and have proposed revisions to the *Food and Drug Regulations* to require clear labelling of priority food allergens (see article on page 27). We've also carried out consultations on food and nutrition, as well as on a proposed approach for regulating health products along their entire life cycle. Third, we've enhanced regulatory cooperation with our international counterparts to gain efficiencies and improve information sharing (see article on page 37).

HG: Let me add a few examples. The *Chemicals Management Plan* (CMP), mentioned earlier, is a program of Health Canada and Environment Canada that aims to assess and manage the risks, by 2020, of all chemical substances categorized under the *Canadian Environmental Protection Act* as potentially harmful to human health or the environment (see article on page 32). The CMP is being watched closely internationally as a more favourable alternative to the system of the European Union, which targets only those chemicals believed to pose a risk.

There's also the proposed *Canada Consumer Product Safety Act*. Under the current *Hazardous Products Act*, Health Canada does not have the power to recall a consumer product that poses a health or safety risk—the Department must negotiate this course of action with the manufacturer. The proposed *Canada Consumer Product Safety Act* would change this. It includes what is called a "general prohibition" against the manufacture, distribution and sale of products that pose, or are likely to pose, a danger to the health or safety of the public. So, the proposed legislation will serve as a safety net that would give Health Canada the power to take action against unsafe products, without the need to have specific regulations in place; this action may or may not include a mandatory recall.

We have also been looking at our regulatory requirements in a way that is "smarter" and less burdensome for industry, and that does not jeopardize our health and safety mandate. The regulatory regime of the Pest Management Regulatory Authority is a case in point. It is now interactive and streamlined, and has increased its efficiency by reducing the administrative burden on industry.

HQ: We have also been looking at our regulatory requirements in a way that is "smarter" and less burdensome for industry, and that does not jeopardize our health and safety mandate. The regulatory regime of the Pest Management Regulatory Agency is a case in point. It is now interactive and streamlined, and has increased its efficiency by reducing the administrative burden on industry.

In reflecting on the experiences to date, what have been some of the lessons learned as we move forward?

HQ: Among other stock-taking activities, Health Canada has initiated the *Risk-Based Regulatory Business Processes Transformation* project. This project aims to integrate, wherever possible, the Department's regulatory activities by focusing on the three pillars of the Action Plan. Our first task was to develop an inventory of all the regulatory activities across Health Canada and to assess the findings against the "three pillars." This is allowing us to identify gaps and lessons learned across product lines (see article on page 9).

MV: We're learning, for example, that as more and more people communicate using the Internet and instant web/messaging tools, it is essential that we modernize how we communicate with and engage stakeholders, parliamentarians and citizens so that we can remain open and transparent throughout the process.

HG: As a closing point, I'd like to emphasize that although we're transforming the way we do business today, this doesn't mean that we will finish and remain static. On the contrary, our decisions and the way we do business will continue to be subject to change as our circumstances continue to evolve. ■

Regulation 101: An Introduction

Linda Senzilet, Applied Research and Analysis Directorate, Strategic Policy Branch, Health Canada

The author acknowledges the assistance of *Nancy Scott*, formerly with the Applied Research and Analysis Directorate, Strategic Policy Branch, Health Canada, and *Isabelle Gervais*, formerly with the Legislative and Regulatory Affairs Division, Strategic Policy Branch, Health Canada.

Regulation is a key way by which governments work to protect the health, safety and socioeconomic well-being of Canadians, as well as Canada's natural environment. This article introduces the regulatory process, including the steps that departments and agencies must follow in developing and approving regulations, as well as measures that can be taken to foster compliance with, and enforcement of, the regulations.

Canada's regulatory system plays a role in virtually every aspect of our lives, from the products and services we buy and the medications we take, to the food we eat and the vehicles in which we travel. It also contributes to ensuring a fair and efficient marketplace for industry and consumers, and plays a role in creating a climate conducive to trade and investment.[1]

A broad range of instruments and tools is available to federal departments and agencies to achieve their public policy objectives. **Regulatory instruments** include legislation and regulations that are legally binding; **non-regulatory instruments** are less formal tools (such as economic incentives or disincentives, voluntary standards or codes of conduct for industry, and public education campaigns) that encourage or discourage particular behaviours or actions. In selecting the right mix of instruments to use, regulators must take into account a variety of factors, including the level of risk to be addressed.[2]

What Are Regulations?

In its broadest sense, regulation is a principle, rule or condition that governs the behaviour of citizens and organizations.[3] Speaking more narrowly, a regulation is a legally binding instrument, one of the many instruments that the government uses to achieve its policy objectives and to improve Canadians' quality of life.

Regulations are made in order to put into effect the purposes and provisions of an Act; they are a form of law and they have the force of law. The rules that they set out usually apply generally, rather than to specific persons or situations.[3] In Canada, regulating occurs within the context of our parliamentary democracy and the rule of law. Regulations are developed by persons or bodies to whom Parliament has delegated authority in an Act, such as the Governor-in-Council, a Minister or an agency.[3]

Did you know?

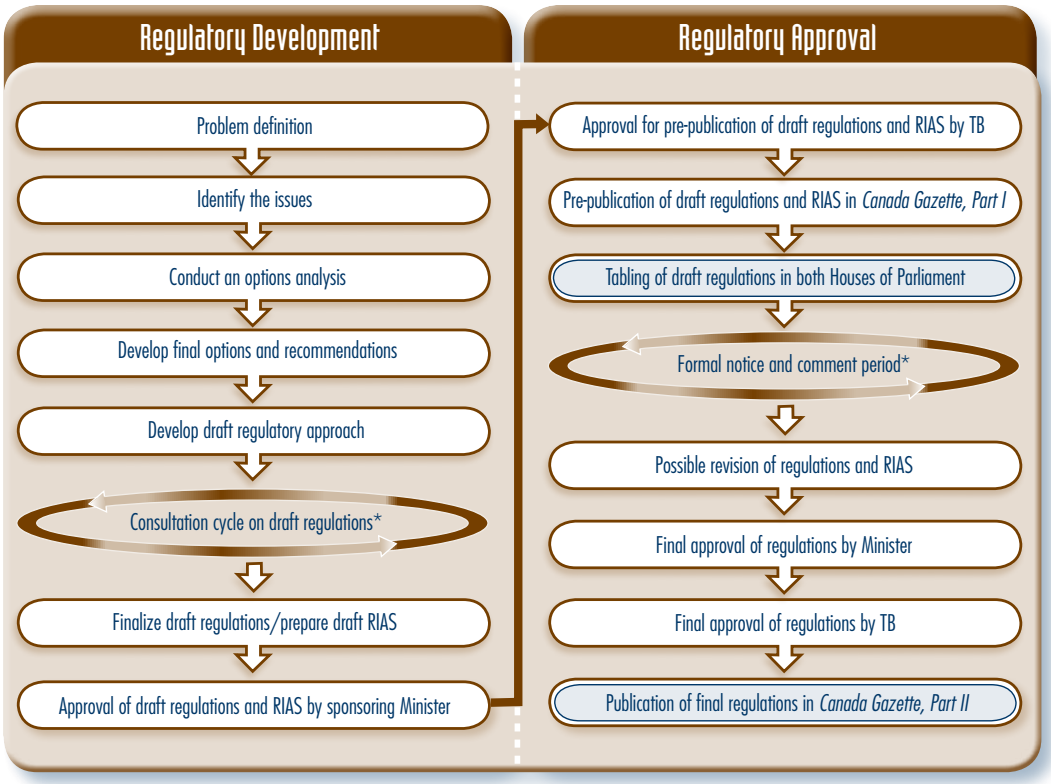
The ***Canada Gazette*** is the official newspaper of the Government of Canada. It serves as a consultative tool between the Government of Canada and Canadians. Proposed regulations are published in *Canada Gazette, Part I*, giving interested groups and individuals, and Canadians in general, a final opportunity to provide comments at the last stages of the regulation-making process, before they are enacted and published in *Part II* of the *Canada Gazette*.

A Broader, More Streamlined Approach

In 2007, the Government of Canada implemented the *Cabinet Directive on Streamlining Regulation* (CDSR), a performance-based regulatory system designed to achieve public policy objectives in health, safety and security, the quality of the environment, and the social and economic well-being of Canadians.[4]

Introduction of the CDSR marked a shift away from the previous narrow focus on regulatory development toward a broader approach that requires ongoing consultation with affected parties throughout the regulatory cycle—from development of regulations through implementation, evaluation and review. It also emphasizes the clear identification of issues, careful consideration of instrument choice (among regulatory and non-regulatory instruments) and the determination of feasible and measurable outcomes when setting objectives.

Figure 1 Steps in Developing and Approving Regulations



A Regulatory Impact Assessment Statement (RIAS) is developed by the responsible department or agency to provide a non-technical synthesis of information for the various users about the issue being regulated, the reason for the regulation, the government's objectives, the costs and benefits of the regulation and who will be affected, who was consulted in developing the regulation and how the government will evaluate and measure performance of the regulation against its stated objectives.[5]

Treasury Board (TB) of Canada is a Cabinet Committee responsible for recommending regulatory proposals for approval by the Governor in Council. Its administrative arm, the Treasury Board of Canada Secretariat (TBS), is responsible for ensuring that the analysis that departments and agencies provide on policy and regulatory proposals is consistent with the commitments and directions set out in the CDSR, and that it effectively supports ministerial decision making.[4]

Source for Figure 1: Adapted from Health Canada, 2004.[6]
** Although "formal" consultations occur at specific steps in the regulatory process, Health Canada consults with stakeholders and the public at other points, as appropriate.*

The process at a glance: developing and approving regulations

The responsible department or agency conducts an assessment of the problem, options and available tools; then, the instruments that are appropriate given the degree and type of risk to the health and safety of Canadians—often a mix of regulatory and non-regulatory tools—are selected.[2] In the process of determining whether and how to regulate, departments and agencies are required to assess the costs and benefits of possible regulatory and non-regulatory measures, including government inaction.[4] If they decide to develop regulations, departments and agencies must meet the requirements of the regulatory approval process as mandated by the *Statutory Instruments Act* and the *Statutory Instruments Regulations* (see Figure 1).

Regulatory Compliance and Enforcement

Once regulations come into force, the initiating department or agency is responsible for fostering compliance with them. Compliance is related to the extent to which affected parties are familiar with and understand the rules, the extent to which they agree to comply with the rules, and their capacity to respect the rules (e.g., whether they have the financial means to put the required systems into place).

The department or agency usually uses a combination of means to foster compliance, including communicating the requirements to affected parties (e.g., through published bulletins) and by verifying compliance (through inspections, compilation of statistics, consultations with industry and creating obligatory disclosure, such as through adverse drug reaction reports). It can also use economic means, such as providing monetary rewards, tax advantages, subsidies and loans for those in compliance.

Similarly, in the event of non-compliance, the department or agency has a range of methods at its disposal, including modification of requirements (e.g., to protect industry against lawsuits and sanctions in the case of voluntary disclosure), persuasion (such as negotiated agreements and formulation of recommendations, including recalls/withdrawal of a product from the marketplace), and sanctions or cessation of regulated activity (e.g., fines, suspension or revocation of licences). ■

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Improving Together: Transforming

Health Canada's Regulatory Business

Paul Glover, Assistant Deputy Minister (ADM), Healthy Environments and Consumer Safety Branch, and ADM champion for Risk-Based Regulatory Business Transformation (RBRBT), and **Hélène Quesnel**, Director General (DG), Legislative and Regulatory Policy Directorate, Strategic Policy Branch, and DG lead for RBRBT

The authors gratefully acknowledge the contributions of staff from across Health Canada's regulatory community who participated in the compilation of the Regulatory Activities Inventory, as well as the insights and leadership provided by the Director Generals' RBRBT Working Group and its Secretariat.

This article introduces work that is underway—at a departmental level—to respond to many of the trends and pressures in the regulatory environment that will be explored in this issue of the Bulletin.

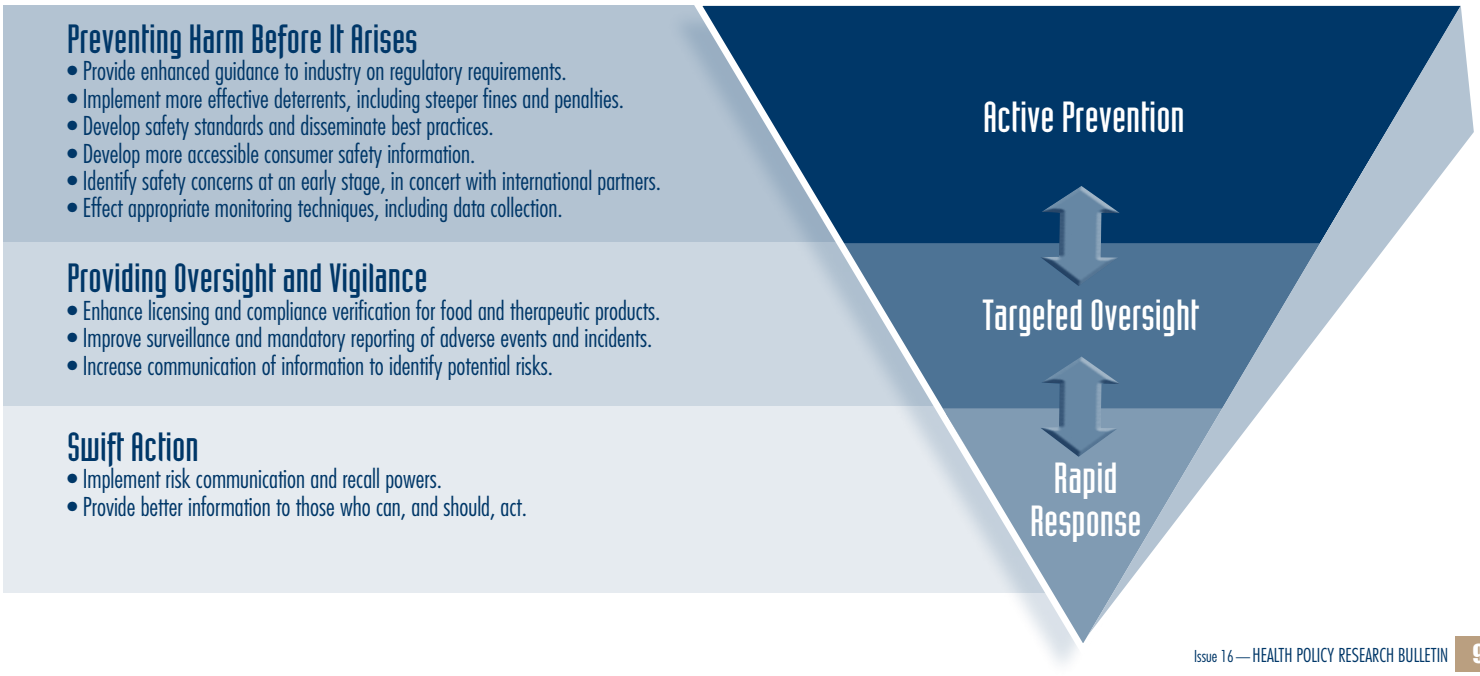
Vision for Risk-Based Regulatory Transformation

Improving Together is a Health Canada initiative that aims to build a more collaborative, accountable and results-driven culture within the Department. Nine key areas of improvement have been identified. One of these areas is Risk-Based Regulatory Business Transformation (RBRBT). Simply put, RBRBT is about improving—on an ongoing basis—how the Department carries out its regulatory responsibilities in order to best respond to an evolving and dynamic regulatory environment. RBRBT envisions risk-based decision making that is:

- *Focused on three pillars of action—active prevention, targeted oversight and rapid response* (see Figure 1). These pillars originated with the *Food and Consumer Safety Action Plan*,[1] but can be applied more broadly across all regulatory activities.
- *Coherent and consistent* along the regulatory continuum of activities (see Figure 2).

Where possible, RBRBT calls for more streamlining and integration of regulatory activities across the Department. It also seeks to leverage Information Management/Information Technology enablers to better carry out the Department's health protection and promotion responsibilities.

Figure 1 Three Pillars of Canada's Food and Consumer Safety Action Plan



The Regulatory Activities Inventory

One of the first tasks of the RBRBT Working Group was the creation of a departmental regulatory activities inventory. The goal was to identify and reflect on gaps, strengths, best practices and opportunities. The inventory confirmed that the Department's regulatory modernization challenge is not *what* it does, but rather *how* it delivers its programs and services.

Active prevention

Analysis of the inventory indicated that the bulk of Health Canada's regulatory activities are generally focused where they should be—on upstream activities under the pillar of **active prevention**. However, there is scope for more integrated and coordinated approaches. In practice, this entails, among other things, identifying ways to better communicate with Canadians and stakeholders as a single department, rather than as a collection of regulatory programs and branches. One reason this is so important is because some products regulated by Health Canada now cut across the Department's traditional business lines.

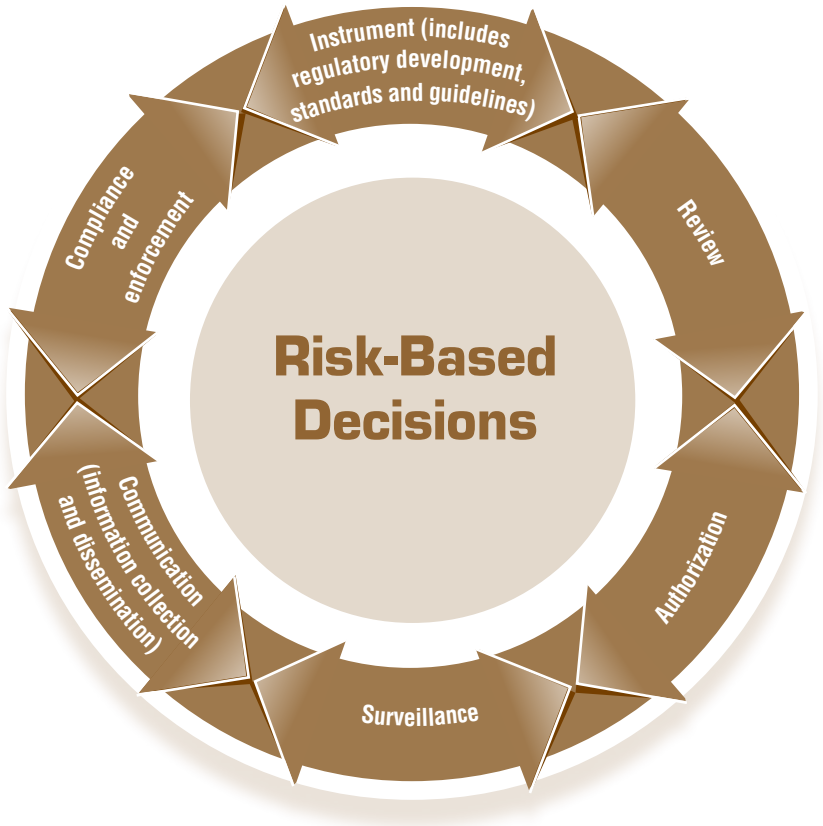
Targeted oversight

Targeted oversight is key, as the data collected (e.g., human exposure to chemicals in the environment, adverse drug reactions, incident reporting regarding a consumer product) helps to determine if active prevention activities are working and when the Department may need to "ramp up" efforts to effect rapid response. Analysis of the inventory has pointed to the potential for synergies to better leverage existing information from partners such as the provinces/territories and international agencies. It has also suggested that the Department needs a clearer sense of what type of information is being collected, how it is being used and how it could be used more effectively (e.g., by more broadly sharing industry compliance data).

Rapid response

Analysis of the inventory has suggested that in the area of **rapid response** (e.g., product recalls and warning messages to the public), greater consistency is required at a departmental level regarding "what," "where," "who," "why" and "how" these types of activities are initiated. This would allow for swifter action, where necessary, and greater transparency to help instil more confidence in those whose lives and businesses are affected by Health Canada's decisions.

Figure 2 Health Canada's Product Life-Cycle Approach to Regulation



The Way Forward

Analysis of the inventory, as well as discussions held to date, point to opportunities for improvement in a number of areas. RBRBT initiatives build on lessons learned and best practices from Health Canada and beyond and focus on three streams of work, which are outlined below along with some concrete examples of the important work already underway.

Streamlined regulatory processes and horizontal decision making

This stream of work will address the need for greater capacity in key areas (e.g., Cost-Benefit Analysis and Performance Measurement and Evaluation Plans—see the *Cabinet Directive on Streamlining Regulation*[2]), as well as the time and resources it can take to develop regulations. Initiatives range from additional

training for regulators to identifying process efficiencies (e.g., exploring with Treasury Board Secretariat whether the *Canada Gazette* process could be shortened in cases where it can be demonstrated that substantial consultations have already taken place). As well, as a result of RBRBT, the Department's Senior Management Board will play a greater role in regulatory decision making, including helping to determine priorities and allocating resources based on risk.

Strengthened risk-based regulatory policies

A suite of new policies and tools is being developed to bring greater coherence in terms of how activities across the regulatory continuum are carried out in Health Canada. Health Canada's policies to provide a framework for compliance and enforcement functions, as well as for public access to health risk information, for example, are important innovations. These policies will not only assist Health Canada regulators, but will also mean greater certainty for its stakeholders because they will explain how and why regulatory decisions are taken.

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Improved engagement and communications

Health Canada's regulatory mandate is at the heart of what it does every day to serve and protect Canadians. The RBRBT Working Group is committed to reaching out to engage the perspectives and talents of the broader departmental community in an agenda of continuous improvement. It also needs to harness "outside-in" perspectives, including the views of the Department's many stakeholders (e.g., the public and regulated parties). *Improving Together* implies working better with Health Canada's partners across and also beyond the Department. Broadening and deepening engagement on RBRBT will be fundamental in order for culture change to take root over the longer term. ■

@ *Please note: Full references are available in the HTML version of this issue of the Bulletin: http://www.healthcanada.gc.ca/hpr-bulletin*

The *Consumer Information Strategy* and the Consumer Safety Portal

The *Consumer Information Strategy* exemplifies the type of innovation that RBRBT is seeking to foster. Part of the *Food and Consumer Safety Action Plan*, the strategy includes a new single "window" on the Health Canada website that offers easy access to clearly written information about consumer products. The new Consumer Safety Portal (http://hc-sc.gc.ca/cips-icsp/index-eng.php) is a joint project under *Improving Together*, led by the RBRBT and the Communications and Consultations Working Group. In addition, social media applications (social bookmarking, RSS feeds and Twitter) are being tested so that the Department can learn how to extend the reach of its information.

Trends and Pressures **Driving** Regulatory Modernization

Elizabeth Toller, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada

Canada's regulatory systems for food, consumer and health products must keep pace with the significant contextual changes within which Health Canada operates. This article provides an overview of these changes and describes the pressures that are being put upon regulators by the evolving interests and expectations of consumers and industry.

The regulatory context within which the federal government operates has changed greatly since the legislative basis for the food, health and consumer safety system was created over 50 years ago. Regulators responsible for helping Canadians to maintain and improve their health must anticipate and respond to a variety of trends and pressures that evolve over time in the regulatory landscape.

This article takes a closer look at these drivers, clustered into six themes, and how they work in concert to inform how our regulatory system needs to change in order to be responsive today and in the future.

Demographic Patterns and Trends

A number of demographic trends contribute to the pressure to modernize the regulatory regimes for food, health and consumer products. The aging of our population and the increasing rates of immigration are of particular importance. These examples will help to demonstrate how evolving population characteristics have an impact on patterns of disease prevalence, and thus on consumer demand for certain health products and therapies.

Over the next two decades, as baby boomers grow older, the age profile of Canada's population will change dramatically. Between 2006 and 2026, the number of seniors is projected to increase from 4.3 million to 8.0 million, and seniors will represent 21.2% of the Canadian population (up from 13.2%).[1] Not only do seniors represent an ever-growing proportion of the population, they have a higher life expectancy than past generations did.

Although today's seniors are living longer than in past generations, they are not free of the diseases associated with aging; in fact, their health needs represent an important pressure driving the demand for certain medications. For example, in Canada, expenditures for cardiovascular medications more than doubled between 1996 and 2001.[2] While greater use of medications is often linked to improved health outcomes, it can also put pressure on the regulatory system to ensure timely access to new, safe and effective therapies. It also highlights the importance of regular post-market surveillance of medications that reduce morbidity and mortality.

Canada's demographic landscape is also becoming increasingly diverse due to growing rates of immigration. The number of foreign-born people in Canada has nearly tripled during the past 75 years.[3] Between 2001 and 2006, Canada's foreign-born population grew by 13.6%, four times faster than the growth of the Canadian-born population of 3.3% during that period.[3] New Canadians come from a variety of regions and population groups, each with its own disease patterns. For example, up to 77% of new Canadians come from populations that are at higher risk of developing type 2 diabetes, including people of Hispanic, Asian, South Asian and African descent.[4]

These changing dynamics of Canada's demography mean that regulators must address a multitude of health and safety issues that pertain to a more diverse population than ever before.

Changing Patterns of Disease

A changing population profile means that the prevalence of chronic and infectious diseases is also evolving, and that new health issues will continue to emerge. As disease patterns shift and patients' needs for products change, regulators must keep pace with innovation to be able to safeguard the quality, safety and efficacy of newly developed products and therapies.

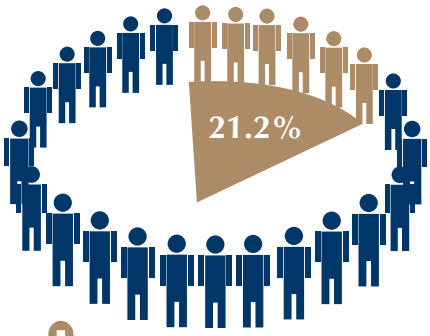
Rates of obesity and chronic diseases, such as cancer, type 2 diabetes and cardiovascular disease are on the rise: in 2004, the combined overweight/obesity rate for Canadian boys and girls was about 70% higher than it had been in 1978–1979, and the obesity rate alone was 2.5 times higher.[5] As obesity is a risk factor for many chronic illnesses, the profiles of these illnesses are expected to change as these children become adults.

By 2011, the number of Canadians diagnosed with diabetes (including type 1* and type 2, but excluding gestational diabetes) is expected to be about 2.6 million—representing an average annual increase of almost 7% and an increase of approximately 33% since 2006.[4] Of particular concern are rates of type 2 diabetes among First Nations and Inuit. This disease was unknown in this population 50 years ago; however, rates are now three to five times higher among First Nations than among the overall Canadian population and are increasing among the Inuit.[6,7,8]

At the same time that the incidence rates of certain chronic diseases are going up, survival rates are also increasing—likely because of improvements to health care and the increased availability of treatment options. Consequently, the number of people living with these chronic diseases will increase, further driving up the demand for therapies.

Incidence patterns for infectious diseases are also changing, as seen, for example, in the arrival of emergent communicable diseases such as Severe Acute Respiratory Syndrome (SARS)[6] and in the re-emergence of traditional infectious diseases, such as measles. (For example, from 2001 to 2005 there were an average of 10 measles cases reported in Canada per year, but in 2007 alone there were 101 reported cases.[9]) As well, recent events related to food safety have highlighted the threats associated with outbreaks of foodborne illness.

In addition, there are increasing risks from illnesses that cross local and international boundaries. For instance, regulators must anticipate and respond to emerging public health issues, such as the recent H1N1 influenza pandemic, which required timely yet rigorous action to develop, test and approve vaccines and therapies to prevent and control the situation. Hence, an updated regulatory system and instruments are crucial for dealing with evolving challenges and threats to Canadians' health.



Over the next two decades, as baby boomers grow older, the age profile of Canada's population will change dramatically. Between 2006 and 2026, the number of seniors is projected to increase from 4.3 million to 8.0 million, and seniors will represent 21.2% of the Canadian population (up from 13.2%).

Consumer Patterns Are Evolving

The demands and interests of Canadians are critical to the discourse on regulatory modernization. As health practices change, it appears that consumer demands for, and use of, a wider array of health products are increasing. A 2005 study found that per capita spending on prescription drugs in Canada doubled between 1998 and 2004—largely due to increases in the volume of drugs being used.[10] Similarly, just over three quarters (78%) of Canadians aged 12 and older reported using one or more prescription or over-the-counter medications in the last month of 1998–1999.[11] The survey also noted that Canadian seniors and women in general were more likely than others to report using medications.[11] This may be related to the fact that women have a longer life expectancy and report a greater number of chronic health conditions than do men.[12]

In parallel, Canadians have reported an increasing use of alternative and complementary health therapies, such as natural health products, vitamins, minerals and supplements.[13,14] There is also considerably more interest in the health and physiological benefits of food, as awareness of the relationship between diet and disease increases.[15]

As patterns of product use change, demands from increasingly educated citizens for more information are on the rise, as are expectations for improved product

*Due to limitations of current physician billing and hospital discharge abstract data, current case criteria for the National Diabetes Surveillance System do not distinguish between type 1 and type 2 diabetes.

labelling. In one 2008 survey, almost half of Canadians (46%) agreed that there was a lack of consumer information available on the consumer products in question.[16]

Furthermore, Canadians' tolerance for risk also varies across the population and among those with unique health situations, sometimes resulting in conflicting influences on regulatory reform. For example, while Canadian parents demand stricter controls over consumer products for their children, people faced with life-threatening diseases want fewer obstacles to accessing new therapies, some of which are available and approved in other countries.[17] Canadians are also concerned with how regulatory reform will address the social and ethical impacts of the products they use and consume. For example, although the World Health Organization has indicated that genetically modified (GM) foods currently available on the international market have passed risk assessments and are not likely to present risks to human health,[18] many consumers would like GM foods to be labelled as such so that they can make informed purchasing decisions.

Canadians' tolerance for risk also varies across the population and among those with unique health situations, sometimes resulting in conflicting influences on regulatory reform. For example, while Canadian parents demand stricter controls over consumer products for their children, people faced with life-threatening diseases want fewer obstacles to accessing new therapies, some of which are available and approved in other countries.

These trends, considered along with a host of high-profile events (e.g., global withdrawal of certain drugs, high levels of lead found in imported children's toys, national food recalls), have led to pressures on the regulatory system for greater protection and faster response. Public interest has also played a role in galvanizing information sharing and public involvement throughout the regulatory process. Such pressures are driving regulatory reform towards a system that is more open, accountable and transparent.

Advances in Science and Technology

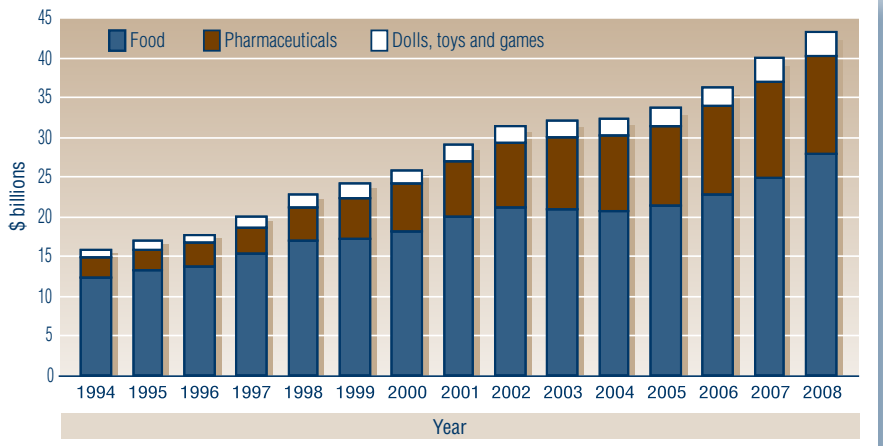
The fast pace of scientific and technological advancement means that consumers have access to an increasing array of health products and therapies. For example, biotechnology offers new knowledge, products and methods to improve health, such as tailored therapies (e.g., pharmacogenomics and proteomics) that promise health benefits in more clearly defined patient populations.[19] Nanotechnology is also gaining ground, as scientists use very small particles to develop materials and products for new medical devices, drugs and food additives.[20] In 2006, biotechnology sales reached $73 billion worldwide, representing 11% of the global pharmaceutical sales ($643 billion). Nanotechnology expenditures are expected to reach $200 billion by 2010.[21]

These opportunities are challenging from a regulatory perspective. For example, critics warn that despite predictions of significant benefits of nanotechnology to society, few data are available on quantitative risk assessments of nanomaterials.[22] There is also a dearth of research on the ethical, legal and social implications of nanotechnology on people's economic, personal and environmental well-being.[23] Similar concerns have been raised with respect to genetically modified and genetically engineered products, which many critics, including members of the public, believe cannot be known in the short term.[24] This puts pressure on regulators to enhance oversight of these products once marketed. It also sheds light on the need to understand and anticipate, as much as possible, the potential effects of emerging technologies on regulatory policy (see article on page 41).

The speed at which new technologies translate to new products entering the market highlights the gaps within the existing regulatory frameworks and approaches. Combination products, such as nano-devices delivering drugs, fall between regulatory regimes (for drugs and medical devices) and thus require different regulatory approaches. This can cause administrative delays in product reviews, and can result in inconsistencies across regulatory frameworks.

A modernized system needs to respond to new technologies and products through consistent, risk-based approaches to regulation; furthermore, regulatory systems must keep pace with what is known about the ethical, legal, scientific and social implications of these technologies.[23]

Figure 1 Selected Canadian Imports, 1994-2008

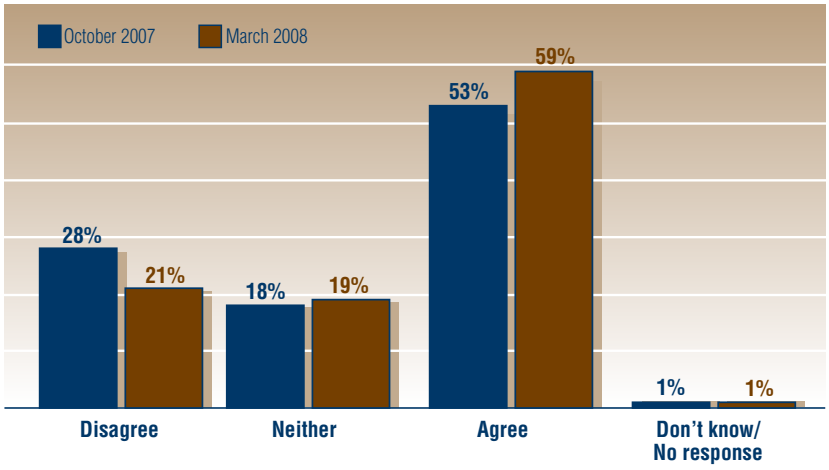


Source: Industry Canada, Trade Data Online.

What Do Consumers Think?

The safety of imported goods that enter the marketplace is of primary concern to Canadians. A recent survey indicated that a majority of Canadians were "worried that unsafe products are being imported into Canada" (53% in 2007 and 59% in 2008).[28] Another survey found that 71% of Canadians reported that when they heard about product recalls they tended to feel more concerned—as recalls demonstrate that unsafe products were getting through the regulatory system.[29] The areas of most concern were food products (for both human and pet consumption), children's toys and drugs.

Figure 2 Consumer Concerns over Products Imported into Canada



Source: Public Opinion Research Issue Paper: Consumer and Food Product Safety, 2009.

Globalization

Providing Canadians with access to safe and effective food, consumer and health products is complicated within the context of the global economy. Until recently, most products were available from limited sources and manufactured in one location; today, production supply chains and consumption networks are more complex and wide-reaching.

Global connections are particularly evident between North American and European drug firms and companies from emerging economies. India and China are two prominent examples—China produced 14% of the world's market of active pharmaceutical ingredients in 2005, and India is one of the largest exporters of finished pharmaceutical products and generic drugs.

Over the last 10 years, the volume of Canadian imports has increased substantially, with products coming from a variety of countries with various safety standards.[25] There has been a steady increase of imports (measured in billions of dollars) of food, pharmaceuticals and consumer products, such as dolls, toys and games, from $15.8 billion to $43.2 billion over the period 1994 to 2008 (see Figure 1).[26]

The changing nature of Canada's imports has exposed Canadians to greater risks from new technologies, counterfeit and contaminated products, as well as products from countries with lesser regulatory standards. A recent poll conducted by Decima Research[27] indicated that Canadians trust Canada's inspection processes, but they are highly concerned about products coming from other countries (see sidebar and Figure 2).

From the regulators' point of view, these global circumstances are driving the need for more active prevention, targeted oversight and rapid response to new health threats arising within the global economy.[25] The complexity of the

global context has also highlighted the importance of international regulatory cooperation to safeguard health and safety standards while also remaining globally competitive (see article on page 37).

Keeping the Regulatory Burden for Industry in Check

While the primary objective of Health Canada's regulatory action is to protect public health, the regulator must also consider the impacts of this action on the global business environment. Regulatory conditions are key drivers for investment and manufacturing decisions, as well as for marketing and commercialization strategies. Some firms are concerned that Canada is viewed abroad as having an overly complex regulatory environment, and that this can be a deterrent to business development in Canada.[30] Slow or delayed market access can also come at a cost to consumers, whose access to new products can be compromised.[25]

These challenges, among others, have contributed to a growing trend whereby industries are reducing their costs by moving the manufacture of their products to emerging markets, such as China, India and Russia, that have strong, developing economies.[21] In a highly regulated sector such as health, a modernized regulatory system can provide a competitive advantage to industry; in today's global marketplace, "industry needs to innovate quickly to compete globally."[25]

Regulatory conditions also affect research and development (R&D) investments and have contributed to the migration of clinical research from Canada to areas where conditions are more favourable and less costly. In 2006, R&D expenditure for pharmaceuticals in Canada was $1.2 billion, representing 8% of sales, down from double-digit figures in the 1992–2002 period.[21] This decline has been attributed, in part, to Canada's high-cost environment for conducting clinical trials, which constitutes 40% of the cost of drug development. With a potential cost savings, many companies have been shifting their clinical trials to countries outside of North America and Western Europe (see article on page 23).

While the primary objective of Health Canada's regulatory action is to protect public health, the regulator must also consider the impacts of this action on the global business environment. Regulatory conditions are key drivers for investment and manufacturing decisions, as well as for marketing and commercialization strategies.

It is important for regulators to work with industry to ensure that safe products are accessible across the global supply chain. The *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH) is one means by which such dialogue is taking place (see article on page 37). The objectives of this forum remain ongoing challenges for regulators: leveraging international consistency in regulation, reducing necessary delays in global development and availability of new drugs, and, most importantly, maintaining safeguards on safety, efficacy and quality of products to protect public health.

Summing Up

The rapid rate of change in all areas of society has been driving the need for, and influencing the direction of, regulatory modernization in health. Public health needs and consumer demands reflect demographic changes. While consumers are asking for stricter controls in some areas, they are also asking for faster access to new, potentially life-saving therapies in others. So, as regulators try to integrate protection, access and innovation, they are recognizing that while there may be tensions, the interests of consumers and industry are not necessarily opposed. Moreover, both groups are demanding a greater voice in a regulatory process that is becoming more open and transparent.

On the supply side, scientific advances, the explosion of new technologies and globalization have created both new products and proponents who are anxious to find efficient access to the marketplace.[17] In such an environment, regulatory regimes must adapt quickly to sustain effective protection for their citizens while keeping pace with innovation.

The trends and pressures described above cut across product lines; however, given the characteristics of the different regulatory regimes for food, health and consumer products, the dynamics of their impacts vary. The articles that follow will examine these differences. ■

Please note: Full references are available in the HTML version of this issue of the Bulletin: http://www.healthcanada.gc.ca/hpr-bulletin

Modernizing Canada's Regulatory Regime for **Pharmaceuticals and Biologics**

Natalie Bellefeuille, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada; **Edward Gertler**, Office of Pharmaceuticals Management Strategies, Strategic Policy Branch, Health Canada; **Maurica Maher**, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada; and **Karen Timmerman**, Office of Policy and International Collaboration, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

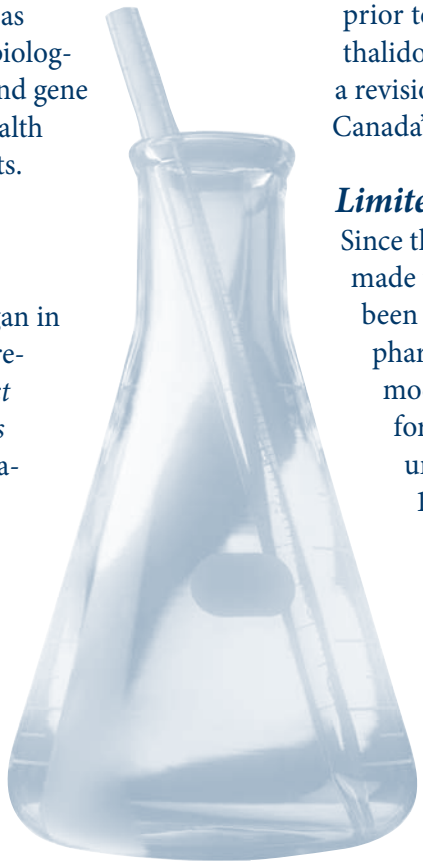
In Canada, pharmaceuticals are regulated under the* Food and Drugs Act. *Established decades ago, the current regulatory regime focuses on the pre-market assessment of drugs. This article traces the steps in the approval of drugs under the current regime and discusses the limitations of a pre-market approach as well as the drivers for modernization. It also highlights Health Canada's project in support of adopting a "life-cycle" approach to regulation, whereby products would be assessed both before and after they are placed on the market.

Under Canada's *Food and Drugs Act* (FDA), Health Canada regulates six broad classes of drugs: conventional pharmaceuticals (such as over-the-counter and prescription drugs); biologics (such as vaccines and blood products) and gene therapies; radiopharmaceuticals; natural health products; veterinary drugs; and disinfectants.

Looking Back in Time

The federal oversight of food and drugs began in 1875, when legislation was introduced to prevent their adulteration. The *Adulteration Act* was replaced in 1920 by the *Food and Drugs Act*, which was aimed at preventing adulteration, unsanitary production and fraudulent labelling. By the late 1920s, regulations developed under the Act established specific requirements for licensing drugs, giving the Minister of Health the authority to cancel or suspend a drug's licence for violations of the requirements.

A significant reworking of the *Food and Drug Regulations* began 20 years later, laying the foundation for the regulations that are in place today. By 1951, manufacturers were required to obtain regulatory approval prior to marketing their drugs. However, the thalidomide tragedy of the early 1960s prompted a revision of the regulations to strengthen Health Canada's regulatory abilities.



Limited amendments have been made

Since that time, targeted amendments have been made to the FDA and its regulations. These have been primarily focused on products other than pharmaceuticals and biologics. For example, modern sets of regulations have been created for medical devices (regulated separately under the *Medical Devices Regulations* since 1998) and natural health products (regulated separately under the *Natural Health Product Regulations* since 2004).

The regulatory regime for conventional pharmaceuticals and biologics, however, remains much the same as it was when it was established in the early 1950s; it is characterized by a licensing system that focuses on

Continued on page 20

How Are Conventional Pharmaceuticals and Biologics Currently Regulated?

Edward Gertler, Office of Pharmaceuticals Management Strategies, Strategic Policy Branch, Health Canada. Portions of this section were adapted from the *Overview of the Canadian Federal Drug Review Process*, by Marilyn Schwartz, Therapeutic Products Directorate, Health Canada, and from the Health Canada publication *Access to Therapeutic Products: The Regulatory Process in Canada.*

Approximately 22,000 human drug products (including biologics and genetic therapies) are licensed for sale in Canada.[1] Many steps are followed between early research and development (R&D) and the point at which a particular drug is available at the corner drug store or in a health care facility. These steps encompass the regulatory decisions made by Health Canada under the *Food and Drugs Act* (FDA), as well as the regulatory and non-regulatory (policy) decisions made jointly or individually by federal, provincial and territorial levels of government (see Figure 1).

Step 1 Pre-Clinical Studies

Pre-clinical studies are carried out to evaluate the safety of a drug and its potential use. They include both *in vitro* (in the test tube) testing and *in vivo* (in animals) testing to assess the performance of the drug, including the existence and extent of toxic effects. If the pre-clinical studies are promising, the trial's sponsor must apply to Health Canada's Health Products and Food Branch (HPFB) for authorization to conduct a clinical trial involving human subjects in Canada. While clinical trials conducted outside of Canada do not fall under Health Canada's regulatory jurisdiction, data generated from such trials are normally included in the evidence base that a manufacturer submits to Health Canada when seeking regulatory approval for a drug.

Step 2 Human Clinical Trials

The requirements pertaining to human clinical trials—which focus on the health, safety and ethical treatment of trial participants—are regulated under the FDA. There are normally three phases of clinical trials that occur prior to market approval:

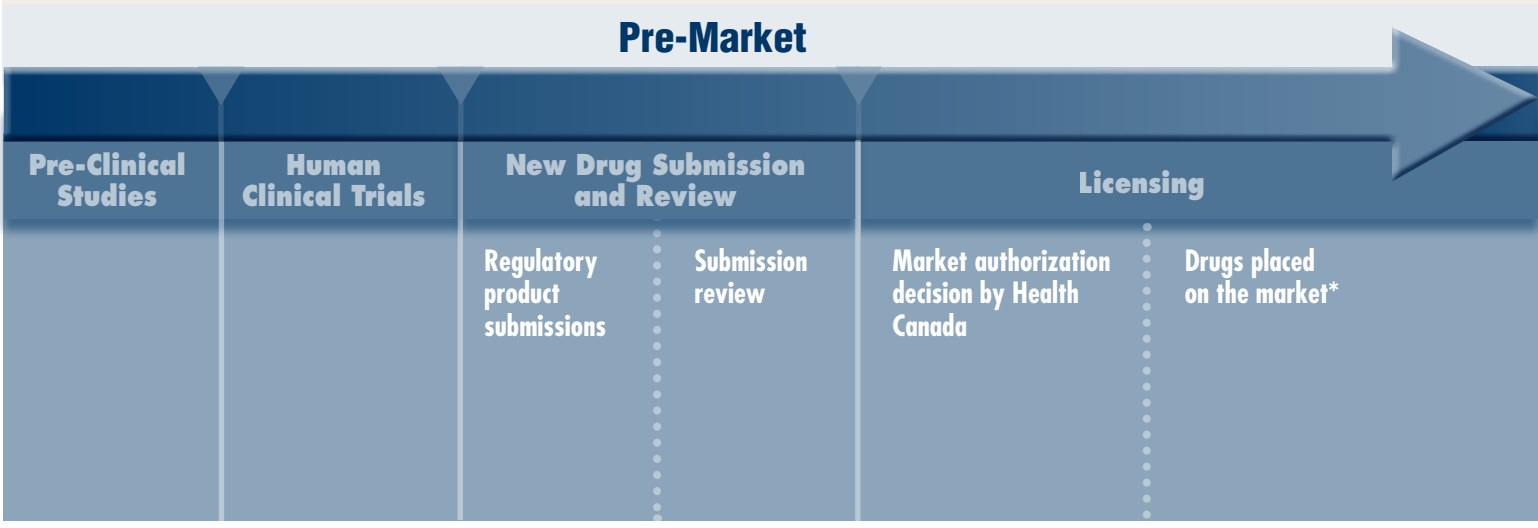
- **Phase I trials** seek to determine whether an experimental new drug product that showed promise in pre-clinical research is safe in humans, what the safe dosage is and whether there are any side effects.
- **Phase II trials** are conducted to determine if a given treatment is effective and to gather additional safety information.
- **Phase III trials** are designed to confirm effectiveness, to monitor side effects and to gather data that inform the safe use of the experimental drug. They normally involve several hundred to several thousand subjects and use randomized, double-blind testing of the drug against a placebo or the best existing approved therapy. (In a double-blind test, neither the researchers nor the research subjects know which subjects are receiving the experimental drug and which are receiving the placebo or best existing approved therapy; this eliminates the possible influence of expectations or subjectivity on the outcomes of the study.)

All drugs carry some level of risk. The overall function of the pre-clinical and clinical trial phases is to ascertain whether the potential therapeutic value of a drug outweighs the risks (such as adverse events or toxicity) associated with its use.

Step 3 New Drug Submission and Review

If a clinical trial shows positive outcomes, the manufacturer assembles the relevant scientific information and files a *New Drug Submission* (NDS) with the HPFB. The Branch reviews the submission—the primary basis upon which it assesses the candidate drug's *safety, efficacy* and *quality*—and determines the drug's risk/benefit profile and whether the identified risks are manageable. The Branch then makes a decision regarding the approval of the drug for market.

Figure 1 The Life of a Drug Under the Current Regulatory Regime in Canada



**Due to marketing strategy and profitability considerations, manufacturers may choose not to market a drug in Canada even once it is has been licensed for sale.*

Step 4 Licensing

For new drugs, a positive decision by Health Canada (in the role of regulator) results in the licensing of the drug for sale in Canada, in the form of a *Notice of Compliance* and the issuance of a Drug Identification Number (DIN). An abbreviated version of the NDS review process is used for generic drugs, whose entry into the Canadian market is also subject to the regulatory requirements related to drug patents under the *Patented Medicines (Notice of Compliance) Regulations*, and to the protection of patented drug manufacturers' confidential data under the *Food and Drug Regulations*. It is worth noting that, due to marketing strategy and profitability considerations, manufacturers may choose not to market a drug in Canada even once it is licensed for sale here.

Common Drug Review

The CDR, which is managed by the Canadian Agency for Drugs and Technologies in Health, was established in 2002. Its objective is to reduce the duplication of reviews while providing participating jurisdictions (except Québec) with common, rigorous reviews of the therapeutic effectiveness and cost-effectiveness of pharmaceuticals based on the best available evidence.[3] CDR recommendations as to whether to list a drug on public drug plan formularies are advisory (not regulatory) in nature, and they are not binding on the participating jurisdictions.

Step 5 Regulation of Patented Drug Prices

In Canada, the prices of drugs with current patents are regulated by the federal Patented Medicine Prices Review Board (PMPRB), whose mandate is to ensure that introductory prices for patented drugs are not excessive and that annual price increases are closely aligned with inflation. The PMPRB, established in 1987 as an independent quasi-judicial body that reports to Parliament through the Minister of Health, currently has no regulatory authority over generic drugs and previously patented drugs whose patents have expired. Prices of patented medicines in Canada are similar to the European average and well below those in the United States. Generic drug prices in Canada, on the other hand, generally exceed international median prices, including American generic prices.[2]

Step 6 Public and Private Drug Plan Decisions

Under the *Canada Health Act*, all medically necessary drugs administered in hospital must be insured by provincial and territorial health insurance plans. Prescription drugs provided outside of hospital are beyond the scope of the Act; provincial and territorial governments determine, at their own discretion, whether and under what terms and conditions to publicly fund prescription drug coverage. As well, the federal government provides drug coverage to federal populations for which it is responsible, including First Nations and Inuit, the Armed Forces and veterans. While each jurisdiction has traditionally had its own process for deciding whether to cover a given drug, the federal, provincial and territorial health ministers agreed in 2001 to launch a Common Drug Review (CDR) (see sidebar).

Step 7 Post-Market Activities

While the current federal regulatory function is focused on the steps leading up to a drug's approval for market, Health Canada is also responsible for the surveillance of the safety and effectiveness of products once they are on the market. Among other activities, Health Canada monitors and collects adverse reaction and medication incident data in order to communicate alerts to health professionals and to the public.

If a drug is found to be unsafe, Health Canada can ask the manufacturer to voluntarily recall existing stocks from pharmacy shelves. However, there is currently no federal regulatory power in Canada to compel the recall of the remaining stocks of a drug from pharmacy shelves; such recalls depend instead on cooperative, voluntary actions by the manufacturer.

Post-Market

Regulation of Patented Drug Prices	Public and Private Drug Plan Decisions	Post-Market Activities
Price review (PMPRB)	Common Drug Review	Real-world use: prescribing practices and patient utilization
	Listing and reimbursement decisions	Collection and communication of Adverse Drug Reactions and other information
	Provincial/territorial policy decisions and formulary-related statutes and regulations	Withdrawal of products from market (e.g., if drug is found to be unsafe)

Source: Adapted from Health Canada, Access to Therapeutic Products: The Regulatory Process in Canada, 2006.[1]

Continued from page 17

pre-market activities. Under this regime, a manufacturer must meet a number of obligations before being allowed to market a drug. Once a drug is on the market, Health Canada has limited ability to monitor its safety and efficacy and to make regulatory decisions (such as mandating changes to drug labelling) on the basis of new information that becomes available about the drug. (An overview of the current regulatory processes for pharmaceuticals and biologics is set out on pages 18–19.)

Drivers for Modernizing Drug Regulation

Our understanding of physiology, the pathology of disease and how humans react to medicines has progressed markedly since the 1960s. At that time, it was thought that clinical trials would provide all of the information necessary to assure that a drug would be effective and safe. The following drivers have led to more modern and comprehensive approaches to regulating drugs.

Limitations of clinical trials

Clinical trials are designed to examine products in populations that are as homogeneous as possible. As a result, patients are often excluded from trials on the basis of co-morbid disease, age, sex or additional medication use. This structure supports a clinical trial to answer a research question such as, "Does drug 'A' work as well as drug 'B'?" However, once a medicine is marketed to a wider population, patients who may not have been included in the trials may also receive the drug, which has not been tested with their particular circumstances in mind.

Moreover, clinical trials are not able to detect rare or uncommon safety concerns such as adverse drug reactions or interactions with other drugs. For example, a trial involving 6,000 patients might not detect a serious adverse reaction that occurs with a frequency of 1 in 10,000. Another limitation of clinical trials can be the duration of study. Some medicines, such as those for chronic diseases, may be used for many years by an individual patient. Since clinical trials rarely extend beyond 18 months, there is little long-term safety and efficacy data available at the time the product enters the market.

Limitations of focus on pre-market evaluation

As the amount of information about a drug increases over time, our understanding of the benefits and risks can also grow. The existing focus of the regulatory structure on the pre-market evaluation of products has created numerous challenges regarding the collection, assessment and communication of information about a drug once it has been on the market.

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Supporting patients and health care professionals

Certain diseases like cancer and HIV infection are now considered to be chronic conditions requiring the long-term use of drugs. Patients are increasingly well educated and want to be informed about the availability and accessibility of treatment options so that they can participate in decisions pertaining to their own health care. They also want to be involved in regulatory decisions and in the development of health policy.

Globalization of pharmaceutical manufacturing

The majority of drugs are now produced outside of Canada—even Canadian drug manufacturers often use other countries as a source for the base ingredients. This creates new challenges to maintaining appropriate oversight. In addition, modern legislation is needed to address such issues as counterfeiting, a growing worldwide problem.

Advances in science and technology

Advances in science and technology have had a tremendous impact on how drugs are developed and

manufactured. Although some of the implications of these new technologies are reflected in regulations, many gaps remain (see article on page 41).

A Life-Cycle Approach to Regulation

The regulation of drugs is undergoing rapid, worldwide change in response to the advances in pharmaceutical sciences, drug development and changes in public expectations. Legislative changes have already occurred in the United States and in Europe to support a life-cycle approach to the regulation of health products, given the many advantages of this approach (see sidebar, below).

Anticipated Advantages of the Life-Cycle Approach

- ongoing evaluation of the risks and benefits of a drug throughout its life cycle, a change from the current focus on testing a drug before it is marketed
- new methods to generate evidence about the benefits and risks of new drugs, and the capacity in the regulatory system to consider new types of evidence in making licensing decisions
- better capacity in the regulatory system to plan for, manage and communicate risks about a drug as new information is obtained
- improved access for consumers, patients and health professionals to current and accurate information about drugs throughout their life cycle, so that they can make the most informed decisions possible
- better alignment of Canada's regulatory standards with international standards, recognizing that the development and monitoring of drugs is now happening on a global scale
- improved transparency about, and clear accountability for, decisions concerning the regulation of drugs

The Drug Safety and Effectiveness Network

The proposed Drug Safety and Effectiveness Network, a virtual network to be overseen by the Canadian Institutes of Health Research, will link centres of excellence in post-market pharmaceutical research across Canada. It will complement other Health Canada initiatives designed to strengthen the Department's post-market surveillance of health products.

A consultative approach

To ensure that Health Canada is capable of maintaining and enhancing its reputation as a science-based and reliable regulator, a project was initiated in 2005 to lead the modernization of the regulatory regime for pharmaceuticals and biologics by supporting a life-cycle approach to their regulation (see Figure 2, next page). Under this project, drugs would be assessed both before and after they are placed on the market, with the goal of maximizing benefits and minimizing health risks to Canadians.

A key element of the project was early and frequent consultation with stakeholders, including health care professionals, industry, patient and consumer groups, academic researchers and provincial/territorial representatives. Following a preliminary meeting with a multi-stakeholder group in which participants identified topics of interest or concern (including improving post-market monitoring of drugs), a unique "mock framework exercise" consultation took place in the spring of 2007, involving internal and external (industry) stakeholders. Health Canada regulators worked with industry to respond to regulatory proposals for pharmaceuticals and biologics, with a broad focus on planning for submission applications, licensing/provisional licensing and post-licensing. The process was observed by other stakeholders—health care professionals, patient and consumer groups, provincial and territorial representatives, and academic researchers—who had the opportunity to provide comments, ask questions and speak to issues of importance to them.

Data generated from the 2007 and subsequent consultations have been used to further develop legislative and regulatory reforms. Additionally, consultation data have been supplemented by information on regulatory processes and best practices in other jurisdictions to help ensure

that Canada is aligned internationally wherever possible. Links have been made with the U.S. Food and Drug Administration, the European Medicines Agency and the Therapeutic Goods Administration of Australia. Project team members have also met with staff of counterpart organizations in the U.S. and Europe as they have undertaken major legislative changes in the area of post-market activities.

Results and Next Steps

Following the consultations, Health Canada decided to move forward on modernizing its legislation. In April 2008, the Department tabled a bill (Bill C-51) containing proposals to amend the *Food and Drugs Act*, which included the following key elements:

- the application and issuance of clinical trial authorizations, market authorizations and establishment licences
- a set of ministerial powers aimed at supporting the ongoing evaluation of pharmaceuticals and biologics throughout their life cycles
- comprehensive prohibitions and a modernized enforcement and penalty scheme, including the federal power to recall the remaining stocks of a drug from pharmacy shelves once it has been taken off the market due to safety concerns

Bill C-51 was debated in Second Reading in June 2008. While it died on the Order Paper when Parliament was dissolved for a federal election in fall 2008, the Government has since communicated to Canadians that it remains committed to moving forward with modernizing the legislation. The Department will continue to consult with its stakeholders to obtain input and feedback on the key elements of modern regulatory frameworks. ■

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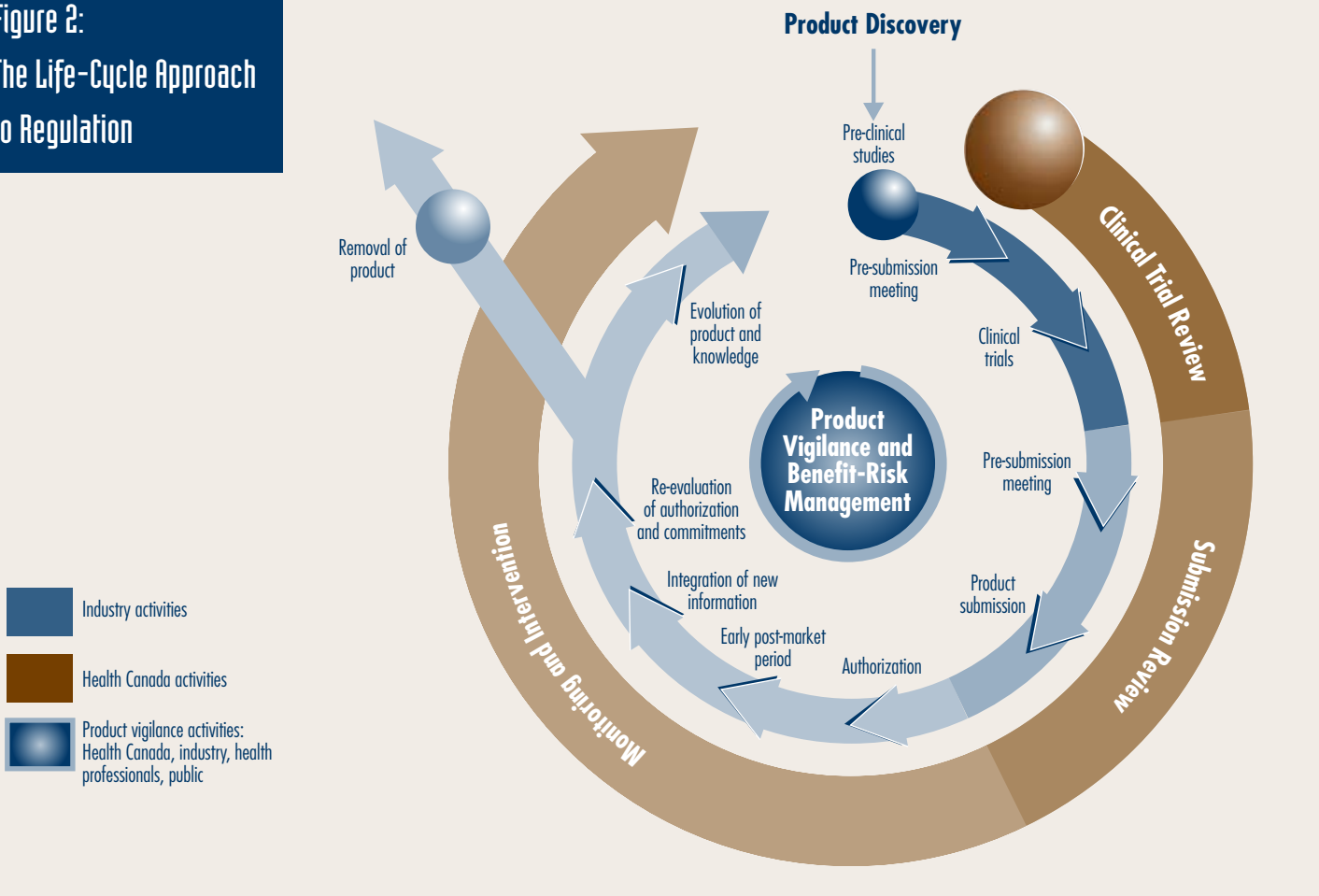
Figure 2: The Life-Cycle Approach to Regulation



Evaluating the Impacts of the 2001 Clinical Trial Regulations

Xuzhen Zhang and **Igor Zverev**, Applied Research and Analysis Directorate (ARAD), Strategic Policy Branch, Health Canada, and **Charles Mallory**, formerly with ARAD

Under the* Cabinet Directive on Streamlining Regulations, *Health Canada, like other federal departments, has committed to undertake an evaluation of the impacts of its regulatory changes. This article describes the evaluation of the Department's updated clinical trial regulations, which came into effect in 2001.

In 2001, an updated regulatory framework for clinical trials (CTs) came into effect in Canada, with two main objectives: to strengthen protection for human participants, and to attract and sustain investment in research and development (R&D). Health Canada recently evaluated the impacts of these regulatory changes. This article presents the process, results and implications of this evaluation, including a quantitative assessment of the second objective —attracting and sustaining investment in R&D.

Why Are Clinical Trials Important?

Countries compete to attract CTs because they can advance medical knowledge, facilitate access to new therapies and generate new jobs. In Canada, Health Canada reviews and approves a large number of CT applications every year.

A CT is an investigation intended to determine the level of safety and efficacy of a drug, its effective dosages and its potential side effects (see article on page 17). CTs are a compulsory part of the research and development (R&D) process for new drugs. Before reaching the market, a drug must go through pre-clinical studies and Phase I, II and III CTs to investigate its safety and efficacy.

CTs are not required for a generic drug (a drug that contains the same medicinal ingredients as the original brand name drug, but which is generally cheaper in price). Instead, a firm is required to conduct comparative bioavailability studies to demonstrate the bio-equivalence (BE) of the generic version with the innovator product.[1]

The Need to Modernize CT Regulations

CT regulations were initially developed in the 1960s under the *Food and Drugs Act*. Over time, the Act has failed to keep pace with the development of new technologies and with the globalization of the pharmaceutical and biotech industries.

Globalization has been transforming the drug development process and posing additional challenges to regulatory authorities. For example, CTs that had been conducted mostly in North America or Europe were being moved to other parts of the world, where costs were lower and access to patients was easier.[2,3] Given these changes, a couple of key regulatory gaps needed to be addressed:

Regulatory authority and protection of trial subjects: Prior to 2001, the regulator lacked the authority to either enforce compliance with approved trial protocols or identify negligence in reporting serious and unexpected adverse events. Record-keeping requirements were not sufficiently explicit, and there were no formal requirements for review and approval by a research ethics board.[4] These gaps hindered the regulator's ability to protect trial subjects from unnecessary risks.

Review times, innovation and investments: Pre-2001 regulations in Canada were falling behind world standards in terms of target review times. Regulatory modernization was needed to keep up with the changing domestic and international environment, especially in the highly technology-driven pharmaceutical and biotech industries. CTs are expensive and they take a long time to complete. Shortening review times was seen as a possible incentive for drug developers to conduct CTs in Canada, potentially providing Canadians with faster access to new drugs.

Important Changes Introduced in 2001

Among other measures, the 2001 regulatory framework shortened the time to review a CT application from 60 days to 30 days, a move intended to help attract and sustain R&D investment. It also put Canada in line with the U.S. and ahead of the E.U. with respect to the time required for regulatory approval.[4]

A seven-day target was also established for the review of BE studies (for generic drugs) and Phase I CTs. This created a key advantage for Canada compared with other developed countries—neither the U.S. nor the E.U. provided such a competitive regulatory environment for BE trials.[4] With increased human resources devoted to the review process, Health Canada has consistently met these targets.[5]

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Evaluating the New CT Regulations

Changes brought forth by the new regulations affect both the regulator and its stakeholders, including CT subjects, industry, academia and non-governmental organizations (NGOs). In following the *Cabinet Directive on Streamlining Regulations*, Health Canada is committed to assessing the impact of the regulatory changes on its stakeholders and is working to ensure that the CT regulatory framework is flexible, robust and effective in responding to new challenges.

Evaluating the CT regulatory framework is a key objective under the *Blueprint for Renewal*, spearheaded by Health Canada's Health Products and Food Branch (HPFB).[6] Several important initiatives to gather input and feedback on the new regulations have been completed to date:

- In 2006 and 2007, HPFB conducted an electronic consultation and then a workshop to gather feedback on the impact on its stakeholders of the regulatory amendments and to seek advice on improving the CT regulatory framework.
- In 2007, Health Canada held a symposium entitled *Context Matters: Gender, Diversity and Clinical Trials*[7] that brought together 60 participants from across government and academia with CT expertise in ethics, research methods and policy. Participants identified and explored issues related to trial protocol design and the inclusion of diverse population groups in clinical trials. (Health Canada has issued a number

of Guidance Documents pertaining to the inclusion of women, seniors and children in clinical trials.[8,9,10])

- In 2008, a formal study was undertaken on behalf of HPFB by the Applied Research and Analysis Directorate (ARAD) in the Strategic Policy Branch of Health Canada, to quantitatively evaluate the impacts of the regulatory change on domestic- and foreign-sponsored R&D in Canada.

What Did Stakeholders Say?

The electronic stakeholder consultation collected 73 submissions on the impacts of the policy changes, while the related workshop gathered 48 participants representing industry, government, academia and NGOs, who proposed improvements to the CT regulatory framework. Most participants in both consultation processes acknowledged that the 2001 regulatory framework had met its objectives of strengthening protection for CT subjects and of attracting and sustaining investment in R&D. The shortened review period for CT applications received positive feedback, particularly from industry respondents.

Respondents also suggested that additional flexibility was required to address emerging trends such as adaptive CT designs, pharmacogenomics and the needs of specific sub-populations. Stakeholders called for timely provision of guidance documents to help sponsors meet various reporting requirements.[7,11]

Participants in the "Gender Diversity and Clinical Trials" symposium raised such issues as the need to include population subgroups in trials, the need for culturally sensitive health research, and the importance of trial design to address sub-group analysis and statistical power. The input will help inform Health Canada's related initiatives, including the life-cycle approach to regulating drugs (see article on page 17), and the need for improved guidance documents that outline how to comply with government statutes and regulations.[7]

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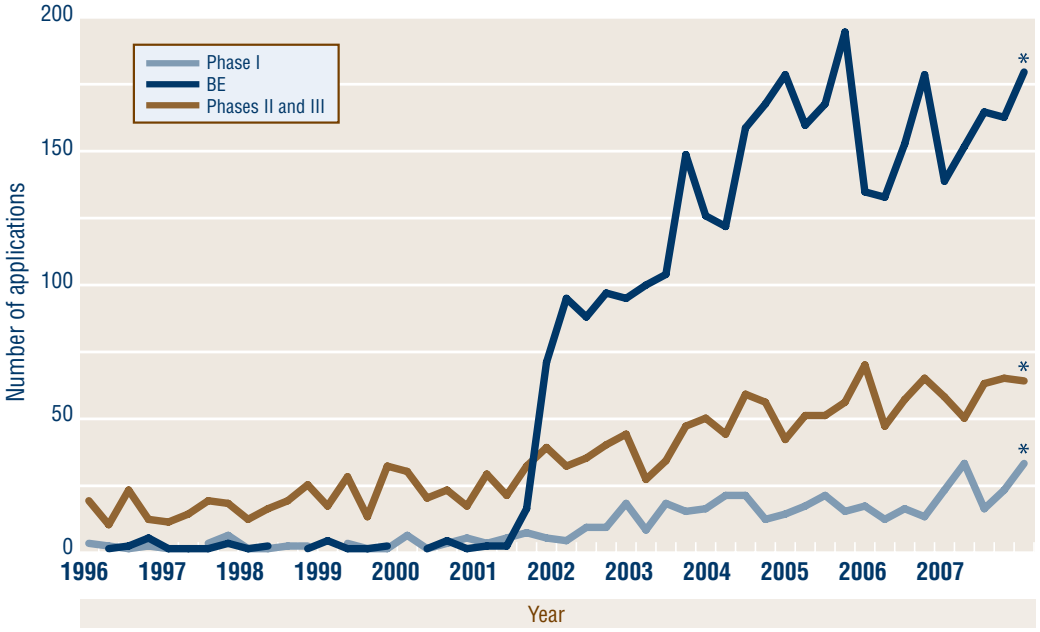
A Quantitative Assessment—What the ARAD Study Shows

The scope of the 2008 ARAD study was limited to a quantitative assessment of the net impacts of the new regulations on R&D activities in Canada. The number of clinical trial applications was used as a measure of the level of R&D activities in Canada. Data were extracted from Health Canada's Drug Submission Tracking System, in which all CT applications submitted to the Department from 1996 to 2007 were recorded. The authors compared and statistically verified the difference in trends in the number of foreign and domestic trial applications by private manufacturers during the six years prior to, and the six years following, the implementation of the new regulations.

Figure 1 Applications for Clinical Trials and Bio-Equivalence Studies by Foreign Sponsors, 1996–2007



** Indicates a statistically significant increase following enactment of the 2001 regulations (according to Chow's test, a statistical tool commonly used in time series analysis to detect the presence of a structural break).*
Source: Health Canada, Health Products and Food Branch, Drug Submission Tracking System.

Differences in foreign and domestic investment

Between 1996 and 2007, about half of all foreign applications came from the United States, with other applications coming from India, Israel and an increasing number of European countries. There was a sharp jump in the number of foreign applications for BE studies immediately after the enactment of the new regulations in September 2001 (see Figure 1, previous page), quite likely as a result of the new seven-day review period. Small increases in foreign investment in Phase I, II and III trials were also seen after the new regulations were enacted; these may have occurred because many foreign sponsors had previously established facilities to take advantage of the seven-day review time for BE trials, thereby gaining familiarity with the Canadian system.

There was a sharp jump in the number of foreign applications for bio-equivalence studies immediately after the enactment of the new regulations in September 2001.

With respect to domestic investment (see Figure 2), Canadian sponsors also responded quickly to the shortened review time for BE trials (as seen by the stark increase in the levels of BE domestic applications following the enactment of the 2001 regulations). Phase I trial domestic applications also showed moderate increases. However, the number of Phase II and III domestic applications did not increase.

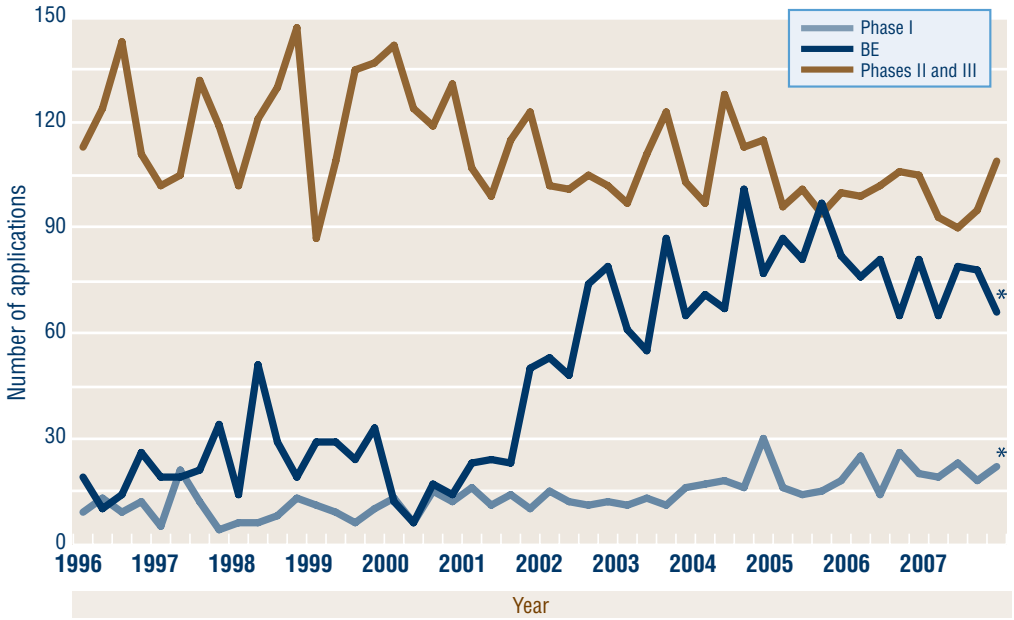
Looking Ahead

Health Canada has assessed the feedback from stakeholders, reviewed best practices in other countries and examined the results of the Department's experience with the 2001 regulatory framework. A 2008 departmental report outlines three main initiatives that Health Canada will undertake to further support the objectives of strengthening the protection of CT subjects and attracting and sustaining investments in R&D in Canada.[7]

First, Health Canada will revise its guidance documents to assist industry in meeting its various regulatory and reporting obligations. Second, the Department will introduce measures to improve the efficiency and effectiveness of processes to strengthen the infrastructure supporting the CT regulatory framework, including electronic receipt and approval of applications, improved business environment, strengthening the reporting of adverse drug reactions and developing stronger partnerships with research ethics boards. Finally, Health Canada will continue to improve access to CT information by encouraging sponsors to register trials on publicly accessible registries; at the same time, it will explore the development of regulatory requirements for registration and disclosure of results.

Health Canada has also pledged to continuously adapt the CT regulatory framework to meet its objectives of strengthening protection for CT trial participants and providing an attractive R&D environment. ■

Figure 2 Applications for Clinical Trials and Bio-Equivalence Studies by Canadian Sponsors, 1996–2007



** Indicates a statistically significant increase following enactment of the 2001 regulations (according to Chow's test, a statistical tool commonly used in time series analysis to detect the presence of a structural break).*

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Modernizing Canada's Food Safety System

Beth Junkins, Food Directorate, Health Products and Food Branch, Health Canada

Few things are more central to the lives of Canadians than the food they eat. Regulatory approaches must keep pace with the many challenges associated with ensuring that our food supply remains safe. This article discusses a modern food safety system, using a case study on food allergen labelling to highlight the regulatory modernization of food and nutrition in Canada.

Canada's Food Safety System: A Shared Responsibility

The food safety system in Canada is a shared responsibility that stretches "from farm to fork." It involves an array of stakeholders, including primary on-farm producers and processors, consumers, industry, non-governmental organizations and various levels of government: federal, provincial, territorial, municipal and regional. At the federal level (the focus of this article) numerous departments and agencies contribute to food safety (see sidebar).

For a food safety system to be effective, participants must understand their roles and be equipped with the tools necessary to fulfil them. One of the federal government's key roles is to provide a regulatory system that is proactive and risk-based, and that has adequate regulatory backstops to ensure food safety.

What Is Health Canada's Role?

Health Canada is one of a number of federal departments and agencies with a food safety role. Key among its roles is the responsibility for setting the standards and policies for the safety and nutritional quality of imported and domestic food sold in Canada. Health Canada works as part of the wider global food safety network that is developing harmonized standards and increasing global understanding of food safety risks, as well as sharing early warnings of potential food safety incidents. During foodborne disease outbreaks, Health Canada works as part of the team of federal partners (Public Health Agency of Canada and Canadian Food Inspection Agency), provinces and territories, and local public health officials to confirm the source of the illness, provide laboratory services and conduct food safety investigations.

Key Federal Players in the Canadian Food Safety System

Health Canada establishes policies, sets standards, and provides advice and information on food and nutrition; it also evaluates the safety, quality and effectiveness of veterinary drugs for food-producing animals.

The **Pest Management Regulatory Agency**, part of Health Canada, regulates pesticides in Canada, setting acceptable levels of pesticide residues on food.

The **Canadian Food Inspection Agency** provides federal food inspection services and enforces the food safety and nutritional quality standards established by Health Canada.

The **Public Health Agency of Canada** mobilizes pan-Canadian action to prevent disease, including foodborne illness, and responds to public health emergencies. It conducts epidemiologic studies and surveillance of foodborne illnesses.

Agriculture and Agri-Food Canada sets the policies to support the economic strength of the sector, and undertakes research to help develop food safety and quality systems.

The Food Safety Environment Has Changed

The current *Food and Drugs Act* and its regulations reflect concerns that existed through the 1950s, 1960s and 1970s—which related to protecting the food supply against adulteration. During those decades, the food supply

How Does Regulating Food Differ from Regulating Drugs?

Regulating food differs from regulating drugs in a number of ways:

- In Canada, only a relatively small number of potentially high-risk food products (such as food additives, infant formulas and novel foods) are required to undergo a pre-market safety review.
- Many key factors affecting food safety cannot be effectively managed through regulation (including those under the purview of the consumer, such as food preparation and food storage in the home); these factors require non-regulatory tools that are more appropriate and effective, such as public education.
- Food-related regulations and policies must consider that a particular food product may be consumed in any quantity by various groups and subgroups of the population. So, for example, a regulation may be required to limit the level of a particular vitamin that can be added to a food.

relied primarily on domestic sources; there were few known microbial hazards and science was only beginning to understand the links between food and health. However, evolving food production practices, scientific and technological advances, changing consumer expectations and product innovation have created new risks and challenges to traditional mechanisms for food safety oversight. Moreover, the globalization of the food supply chain has led to increased accessibility to foods originating from trading partners who vary in their capacity to ensure that the food they export is safe. For example, in 2006, Canada imported food from 186 different countries.

While innovative food products bring new opportunities, they also bring new types of risk. In the complex and evolving global environment of food safety, traditional regulatory approaches may no longer be the most effective.

The Need to Keep Current

While all foods sold in Canada are subject to the *Food and Drugs Act* and its regulations, existing standards and policies have not been able to keep pace with the changing food safety environment. Action is needed that will not only build on the strengths of the existing safety system, but will also use a broader range of risk management tools. The federal government needs to have access to a mix of regulatory and non-regulatory instruments with a range of partners and real-time networks (both domestic and international) who are best placed to intervene and improve food safety rapidly and effectively, using science-based decision processes.

Health Canada's Modernization Strategy for Food and Nutrition

Health Canada has developed a *Regulatory Modernization Strategy for Food and Nutrition* to enhance policies, standards and processes to strengthen food safety (see sidebar, next page).[1] The following case study will illustrate one of the key features of the Strategy: the use of a mix of regulatory and non-regulatory instruments in order to achieve desired public health goals.

Case Study: Food Allergen Labelling

In industrialized nations, as many as 8% of children and 3% to 4% of adults are affected by food allergies that result in reactions ranging from mild to severe.[2] Between 1% and

Goals of Health Canada's *Regulatory Modernization Strategy for Food and Nutrition*

- Improve predictability, effectiveness, efficiency and transparency in the regulatory system.
- Promote regulatory responsiveness to food innovation, and consumer access to foods with assessed health benefits.
- Use of the regulatory toolbox to address food contributors to chronic disease.
- Improve Health Canada's responsiveness to new food safety health risks while managing existing risks.
- Promote a sustainable and integrated system for food safety and nutrition in Canada.

2% of Canadians live with the daily risk of anaphylactic shock and death from food allergies.[3] These people must systematically and diligently avoid the causal foods. For example, an Ontario study showed that, in that province, an average of 2.1 people died each year between 1986 and 2000 of food-related anaphylaxis.[4] It is estimated that there are 150 such deaths per year in the U.S.[5]

Food Allergy and Food Intolerance Incidence Prevention Strategy

Health Canada has historically played a strong proactive role in working with stakeholders to develop risk management approaches to food allergies. The fundamental objectives of those activities have been to minimize risks from inadvertent consumption of causal foods and to maximize the choice of safe and nutritious foods for people with food allergies.

Building on these goals, Health Canada has begun to develop a comprehensive *Food Allergy and Food Intolerance Incidence Prevention Strategy* (FAIPS). This strategy will target action in traditional areas, such as pre-packaged foods over which Health Canada has primary jurisdiction, and in areas where Health Canada could play a supporting role to other federal departments and agencies with respect to such issues as non-packaged foods, the food service sector, improving industry food processing practices and developing new products for food-allergic consumers. When completed, FAIPS will bring together a range of national and international partners working in collaboration under Health Canada's leadership.

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Food allergens used as ingredients

Current Canadian regulations require food ingredients to be listed on the labels of most foods. Since food allergens are regularly used as ingredients in food products, labelling can be a useful tool for food-allergic individuals. Health Canada recently reviewed these labelling regulations with partners to discuss how they could be updated to provide the most effective tool possible to help reduce the risk to food-allergic consumers.

Some products and the components of some ingredients ("ingredients of ingredients" such as flavourings, seasoning and spices) are currently exempt from labelling regulations; this allows components that may cause life-threatening reactions to remain hidden from the consumer. Even when the causal ingredients are listed, the language on labels does not always allow the consumer to identify the causal food. (For example, while "casein" may be declared on a

food label, a milk-allergic consumer may not be aware that casein is a milk derivative.) Moreover, industry is not always clear as to which allergic components should be highlighted on labels.

To respond to the needs of consumers and industry, Health Canada has proposed revisions to its *Food and Drug Regulations* that would address the use of food allergens as ingredients. Published in 2008 in the *Canada Gazette, Part I*, the proposals call for the clear labelling of priority allergens (whether they are ingredients or "ingredients of ingredients") using limited, approved, clear and common language.

Given the potentially life-threatening nature of ingesting food allergens, Health Canada considers regulations to be the instrument of choice in addressing their use as ingredients. The proposed regulations would provide industry, which has the ability to control the addition of ingredients into its food products, with the clarity it needs to help reduce the risks to food-allergic consumers. In addition, improved language on food labels would help these consumers to make safer food choices. Moreover, regulations have a very high likelihood of achieving their objective of addressing serious health concerns.

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Inadvertent addition of food allergens

Food allergens can also find their way into food products as inadvertent additions, through cross-contamination of ingredients at some pre-production point or during the manufacturing process. Avoidance of inadvertently added allergens is critical to the food-allergic consumer. While Health Canada uses regulations to address food allergens added as ingredients, it is not possible to regulate their inadvertent addition to food. Rather, the problem must be approached by selecting the best combination of instruments and a range of actions by industry, consumers' associations and government, in order to develop a strategy that will maximize consumer choice while minimizing risk to the food-allergic consumer.

In 1994, Health Canada established a policy to allow industry to voluntarily use **precautionary statements** to alert consumers to the possible presence of an undeclared food allergen, in cases where the inadvertent presence of the allergen was unavoidable despite all reasonable measures having been taken. The policy does not prescribe the wording of these statements; as a result, there has been a proliferation of various types of precautionary statements (see sidebar). Evidence indicates that food-allergic individuals are increasingly ignoring these advisories and potentially putting themselves at risk.[6,7] A U.S. study of parents with food-allergic children found that the proportion reporting they would never purchase a product with an advisory warning decreased from 85% in 2003 to 75% in 2006.[7]

Precautionary statements—current situation

A recent U.S. study looked at more than 20,000 manufactured products in 99 supermarkets and found that 17% of the products studied used allergen advisory statements, the highest use being in chocolate candy (54%) and cookies (53%).[8] Research emerging from both Canada and the U.S. suggests that industry uses precautionary statements due to concerns about cleaning production lines, difficulties

Examples of Precautionary Statements in Use

- "May contain [allergen] . . ."
- "May contain traces of [allergen] . . ."
- "Manufactured in a facility that also processes [allergen] . . ."
- "Manufactured on shared equipment with products containing [allergen] . . ."
- "Packaged in a facility that also packages products containing [allergen] . . ."
- "Not suitable for people with an allergy to [allergen] . . ."

sourcing ingredients that are free from cross-contamination, and for business reasons, such as avoiding the expense of multiple labels.[9]

Canadian research has shown that the wording of precautionary statements has had a significant impact on how consumers assign risk to particular foods. In one study, parents of peanut-allergic children were shown to most likely avoid foods whose labels contained statements with the words "not suitable" (93%) or "may contain" (87%); however, when the word "traces" was included or the statement cited a "shared facility" with a product of concern, the reported avoidance rate dropped to 72%.[10] These results align with a similar U.S. study.[7]

That U.S. study also looked at the likelihood that the allergen in the advisory was actually present in a sample of 179 products. It found that only 7% of products bearing allergy advisory statements indicating the possible presence of peanuts did, in fact, have detectable levels of peanut residues. However, when residues were present, the levels varied, with values as high as 4,000 parts per million (ppm) in one sample—the equivalent to 1,280 ppm of peanut protein. The study also found that the labels more often ignored by consumers ("shared facility" statements) were used on products that were more likely to contain the allergen.

The precautionary statement "may contain traces of" is widely used in Canada. However, testing done by Health Canada and the Canadian Food Inspection Agency has found the level of an allergen to be as high as 6,500 parts per million (ppm), or 0.65%, in a product bearing this precautionary statement on its label.[11] This level of allergen, for example, peanut protein, in a 40-gram chocolate bar, would be equivalent to 260,000 micrograms of peanut protein. This would be of concern, since subjects in a double-blind, placebo-controlled food challenge have reacted to as few as 100 micrograms of peanut protein.[12]

Upon completion of current research activities, Health Canada will collaborate with food allergy consumer groups and the food industry with the aim of publishing a revised policy and guidelines for the use of food allergen precautionary statements on pre-packaged foods.

Different regulatory approaches needed

Modernizing the approaches to managing potential life-threatening risks posed to food-allergic consumers by allergens in foods illustrates the need to choose the best tools, both regulatory and non-regulatory, to achieve policy goals. On the one hand, when allergens are added as ingredients, a high degree of control can be exerted at the level of the producer; a traditional regulatory approach is a justified and effective mechanism to address this serious health concern. On the other hand, a complex set of factors is at play when addressing the food safety risks posed by the inadvertent addition of allergens, as outlined above. Effective management of this issue necessitates looking beyond traditional regulatory approaches.

Health Canada's strategy for modernizing food and nutrition regulations is helping to bring risk management approaches up-to-date with current needs and challenges. The complex world of food products calls for a regulatory regime that keeps Canada's food supply as safe as possible, while remaining responsive to an increasingly global food industry as well as the changing needs and growing involvement of the public.

In Summary

Health Canada's strategy for modernizing food and nutrition regulations is helping to bring risk management approaches up-to-date with current needs and challenges. The complex world of food products calls for a regulatory regime that keeps Canada's food supply as safe as possible, while remaining responsive to an increasingly global food industry and the changing needs and growing involvement of the public.

As this allergen case study shows, regulators need to go beyond traditional regulatory approaches and consider a complementary suite of actions that involve all players. Food allergen labelling research will help shape policy options that aim to minimize the chances of exposure while maximizing the availability of safe nutritional choices. The lessons learned from this area of food safety can be applied to other food safety and nutrition issues as they arise. ■

@ *Please note: Full references are available in the HTML version of this issue of the Bulletin: http://www.healthcanada.gc.ca/hpr-bulletin*

Canada's Chemicals Management Plan: Regulatory Innovation

Tina Green and **Matthew Tolley**, Safe Environments Directorate, Healthy Environments and Consumer Safety Branch, Health Canada

Canada's* Chemicals Management Plan *(CMP), a program co-managed by the Ministers of Health and the Environment, was announced in December 2006. It is an ambitious program that aims to assess and manage, by 2020, the risks of chemical substances in use in Canada that are potentially harmful to human health or the environment. This article describes the evolution of the CMP as well as the legislation and other tools it uses to manage risks to protect human health and the environment.

Chemicals, People and Lessons Learned

When the industrial production of chemicals first emerged as an important economic sector in the early 1900s, the focus was on the benefits of these modern chemicals and the many products they made possible. The benefits of refrigeration for a household, for example, were significant and immediate. As these new products rapidly proliferated, it never occurred to most people to consider the possible risks—to both humans and the environment—associated with the use of an increasing variety of human-made substances.

Hard lessons and a great deal of scientific study over the years have revealed the importance of looking beyond immediate benefits and evaluating the potential risks associated with exposure to new chemicals. In the later half of the 20th century, we began to understand that both acute and chronic exposures to some chemicals may be linked to cancer, respiratory diseases, developmental and behavioural problems, as well as to impaired immune and endocrine systems. These health conditions not only have an impact on the health of individuals; they also carry costs for our health care system, social services and economy that have a significant impact on our society.

Through the CMP, the federal government has redesigned its approach to setting priorities for managing chemicals in order to first assess them for potentially harmful effects and then manage the associated risks to human health and the environment.

CEPA 1999: A Progressive Approach

In Canada, all levels of government play a part in protecting Canadians against the risks from chemical substances. At the federal level, the *Canadian Environmental Protection Act, 1999* (CEPA 1999) is a key element of the legislative framework for protecting the environment and human health. It came into force on March 31,

2000, following an extensive parliamentary review of the former *Canadian Environmental Protection Act, 1988*.

CEPA 1999 is designed to protect human and environmental health from risks posed by substances, and includes an emphasis on pollution prevention. For the purposes of the Act, substances have been divided into two categories: those new to Canada since 1987 (*new substances*), and the 23,000 chemicals in commercial use before 1987 (*existing substances*). The assessment of both new and existing substances is the joint responsibility of Environment Canada and Health Canada.

While the CMP deals with existing substances, the New Substances Program is responsible for administering the *New Substances Notification Regulations* of CEPA 1999. These regulations ensure that no new substances are introduced into the Canadian marketplace before an assessment of whether they are potentially harmful has been completed, and before any appropriate or required control measures have been taken.

The Categorization Process

In the early 1990s, Canada took stock of the existing chemicals on the domestic market and created the Domestic Substances List (DSL). Most of these 23,000 existing substances, or legacy chemicals as they are also known, were put into use without ever being subjected to a health and environmental risk assessment. While many other countries undertook a similar exercise, some focused on particular substances (e.g., those produced in the highest volume or with the greatest market share). Canada opted for a more comprehensive approach; it became the first country to undertake a systematic examination of all unassessed chemicals and substances that were in use prior to introducing its new substances notification and assessment regime.

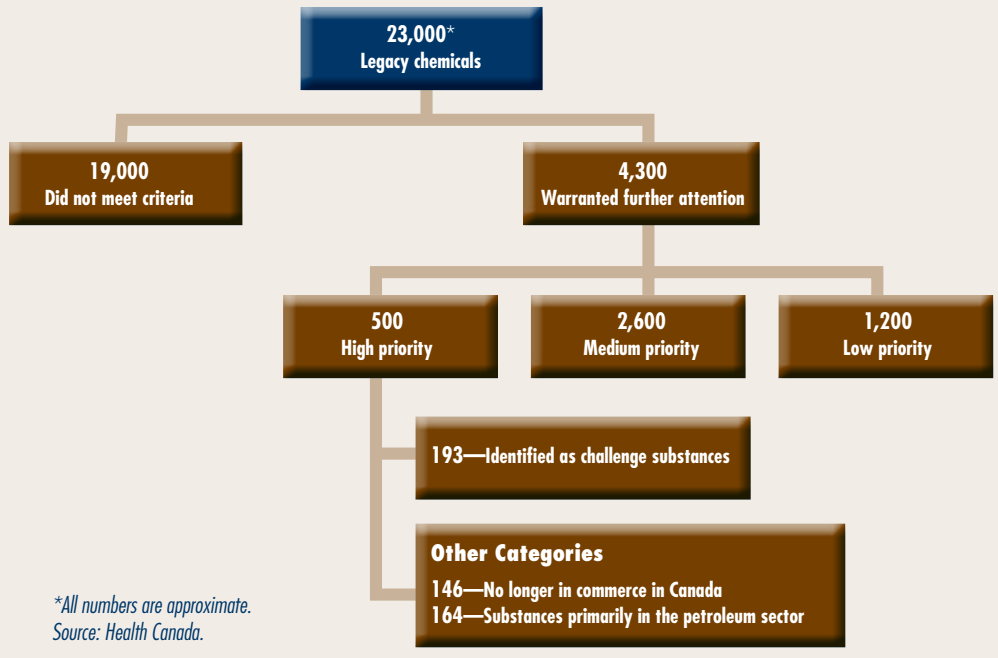
CEPA 1999 required that all existing substances be examined by September 2006 in order to determine if they were potentially harmful to human health or the environment, and to identify which ones warranted further attention. This led to a large-scale priority-setting exercise wherein federal scientists applied a set of rigorous tools to the substances on the DSL to categorize and identify those that were:

- inherently toxic (harmful, by their very nature, to humans or to the environment)
- persistent (take a very long time to break down)
- bioaccumulative (collect in living organisms and end up in the food chain)
- substances to which people might have the greatest potential for exposure

Additionally, some substances were identified during categorization because of the likelihood that children would come into contact with them, including: chemical substances that are likely to be used as colourants in food and dyes in clothing; flame retardants; fragrances and deodorizers; fabric softeners; lotions; and paint and coating additives.

The categorization of existing substances became a major focus for Canada between 2000 and 2006, and was completed on schedule. Out of the 23,000 substances reviewed, 4,300 substances were identified as priorities for human health and the environment by Health Canada and Environment Canada and became the focus for further work under the CMP. Of these, 500 were designated as the highest priorities for immediate action (see Figure 1).

Figure 1 Chemicals Categorization Process: A Large-Scale Priority-Setting Exercise



*All numbers are approximate.
Source: Health Canada.

The *Chemicals Management Plan:* From Knowledge to Action

Canada's CMP was both a response to the findings of the categorization exercise and the next step in the process set in motion by CEPA 1999. The CMP sets out an ambitious objective: to address all chemical substances (including those categorized as high, medium and low priorities) in Canada by 2020. This will be accomplished by accelerating existing activities, reinvesting in science, and developing new and innovative partnerships with industry and with other countries to work collectively towards common goals.

The CMP's launch in 2006 coincided with heightened concern among Canadians about the chemical substances in the marketplace and the increasing expectation that the federal government would provide oversight to reduce the risks to human health and the environment.

The goal of Canada's CMP is, above all else, to protect the health of Canadians and the health of our environment. The CMP is science-based and is designed to protect human health and the environment by:

- taking immediate action on chemical substances of high concern
- undertaking other regulatory activities in specific sectors (consumer products, food, pharmaceuticals, personal care products and pesticides) by using the best-placed Act
- investing in research, including biomonitoring, in order to learn more about chemical exposures and human health impacts, as well as to evaluate the success of control measures

Addressing substances of greatest concern

Of the 500 high-concern substances identified in the categorization exercise, the 193 substances (called challenge substances) suspected of being harmful to human health or the environment that had not been addressed were the highest priorities for risk assessment and appropriate controls (see Figure 1). A challenge was issued to industry to provide new information about how it is using and managing these substances. The information collected on the properties and uses of these 193 substances is being used to make decisions regarding approaches to protecting Canadians and their environment, including the use of federal legislation to impose strict controls on, or even prohibit, certain substances. All 500 of the high-priority substances, however, will be assessed by the end of 2010, and appropriate risk management activities will be identified.

Work under the CMP is not confined to the 23,000 categorized substances; other actions are also being taken. In November 2006, cosmetic regulations were amended to require ingredient labelling on all cosmetic products. Consultations are being conducted with commodity groups and stakeholders to complete health and environmental assessments of more than 9,000 substances used in products regulated under the *Food and Drugs Act* (FDA). In addition, the federal government is working with stakeholders to promote the proper disposal of products regulated under the FDA, such as pharmaceuticals and personal care products, to reduce the burden on the environment.

Under the *Pest Control Products Act*, CMP commitments involve accelerating the re-evaluation of the remaining pesticide active ingredients that were registered before 1995. Health Canada has streamlined processes to accelerate the registration of newer pesticides that replace products and/or their uses no longer considered acceptable. A pesticide sales information database and a mandatory pesticide incident reporting system have also been established; these allow Health Canada to assess health and environmental trends and take regulatory action, when applicable.

What is a chemical?

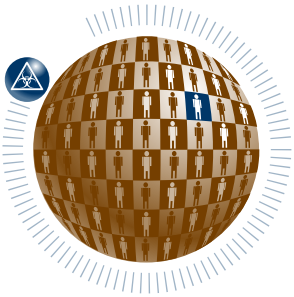
As broadly applied to the chemical industry, a **chemical** or **chemical substance** can be defined as "an element or a compound produced by chemical reactions on a large scale for either direct industrial and consumer use or for reaction with other chemicals."[1] In addition, the by-products of chemical processes or degradation can have impacts on the health of people and the environment, and so may also be of interest for chemicals management.

Using the best-placed Act

The CMP is concerned with improving the safe use and disposal of a range of consumer products and with providing Canadians better information about the contents (ingredients) of products. CMP's innovative approach to regulation supports the use of the best-placed and most effective Act to address the potential risks of a chemical substance. This is important because the government's regulatory actions should be proportional to the identified risks, as well be the most cost effective and efficient in achieving the risk-management objective.

A variety of risk management instruments, including guidelines, codes of practice, pollution prevention plans, environmental emergency plans and regulations, are available under CEPA 1999 and other federal legislation (see sidebar). For example, Canada became the first country to regulate Bisphenol A (BPA), a chemical that may be harmful to infants and the environment. The federal government is acting to address exposure to BPA through a variety of means, including: regulations prohibiting BPA in baby bottles under the *Hazardous Products Act*; setting targets for migration of BPA in food packaging; and placing limits on how much BPA can be in sewage effluent under CEPA 1999.

Health monitoring and surveillance are essential to identifying and tracking human exposure to hazards in the environment and the associated health implications in populations.



Investing in research

Under the CMP there is also new investment in biomonitoring (see sidebar, next page). A key element of the CMP is the monitoring and surveillance of human exposure to harmful chemicals. Health monitoring and surveillance are essential to identifying and tracking human exposure to hazards in the environment and the associated health implications in populations. These data provide the basis for developing sound and effective public health and environmental health policies and interventions, as well as for measuring the efficacy of control measures.

The Canadian Health Measures Survey (CHMS), a national ongoing survey carried out by Statistics Canada in collaboration with Health Canada and the Public Health Agency of Canada, collects information from Canadians about their health. The first cycle of the survey (2007 to 2009), included a biomonitoring component to measure human levels of environmental chemicals in a sample that represents the overall Canadian population.

In the first cycle of the survey, 5,000 randomly selected Canadians between the ages of 6 and 79 years were tested at 15 collection sites. Children aged 3 to 5 years were included in the second cycle of the study that began in

Canadian Legislation Covering Environment and Environmental Health Issues

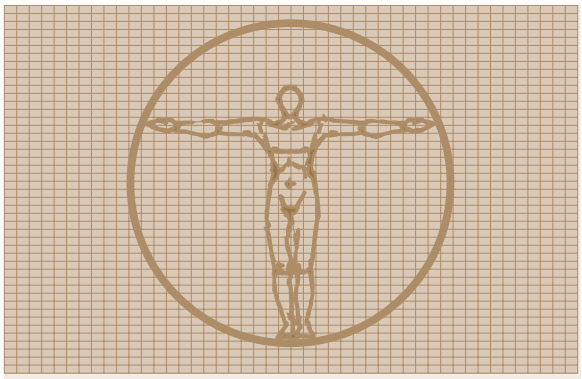
The Government of Canada is responsible for more than 25 different laws covering environment and environmental health issues. Some of these are:

- The *Food and Drugs Act*–regulates food, drugs, cosmetics and therapeutic devices to protect health.
- The *Pest Control Products Act*–regulates pesticides to protect human health and the environment.
- The *Hazardous Products Act*–regulates consumer products that pose a risk to their users.
- The *Canadian Environmental Protection Act, 1999*–creates a regulatory framework to protect the environment and health and to regulate toxic substances.

the fall of 2009. Blood and urine specimens were collected and analyzed for substances such as metals, pesticides, PCBs (polychlorinated biphenyls), BPA, phthalates, and others.

One of the most important contributions of the CHMS will be to establish current population-wide levels for a broad range of environmental chemicals. These baseline data will allow for trends to be tracked and for comparisons between sub-populations in Canada and with other countries. The results will also help to focus future research efforts on the links between exposure and health, and provide information to guide regulatory and other action by governments. For example, preliminary results from the CHMS show a large decline in population blood lead levels since the 1970s, and indicate that less than 1% of Canadians have blood lead concentrations above the Health Canada guidance value.[2] Moreover, the set of environmental chemicals that are being measured in the CHMS will be periodically reviewed in subsequent cycles of the survey.

In addition to the national biomonitoring initiatives such as the CHMS, other research, such as exposure studies, are targeting sub-populations of interest. Two anticipated benefits of all biomonitoring research are the advancement of relevant scientific methods and techniques and the development of better tools to interpret and communicate study results.



Human Biomonitoring

Human exposure to chemicals is an important area of focus for the federal government. Human biomonitoring is the measurement of a chemical and its by-products in people. Measurements to indicate how much of a chemical is present in a person are usually taken in blood and urine and sometimes in other tissues and fluids such as hair, nails and breast milk.

Human biomonitoring data not only establish baseline levels of chemicals in Canadians and detect trends in exposure over time and by geographical region, they also identify populations that might have higher levels of specific substances and who may be at higher risk of adverse health effects. Data are also used for a variety of other purposes, including to learn more about the relationship between the amount of exposure (i.e., the dose) and health effects, and to identify substances not previously thought to be of concern.

Benefiting from Collaboration

The CMP involves a remarkable amount of cooperation and draws on the expertise and resources from many branches of Health Canada and Environment Canada. Through collaboration, the CMP provides a modern approach to chemical substance management that is risk-based and that uses scientific assessment and monitoring, combined with a variety of tools for protection. Decisions made through the CMP rely first and foremost on scientific evidence. However, while the science determines the degree of risk, stakeholders, through forums such as the Challenge Advisory Council, contribute valuable information and expertise useful for managing identified risks.

The CMP utilizes a horizontal approach that engages all sectors. The federal government is working with industry to develop and codify sound management practices that protect Canadians and their environment, in some cases reducing the need for regulation. Recognizing the need for these actions, industry has been working to find solutions in many areas. The federal government also seeks to balance the diverse concerns of other stakeholders, including health and environmental organizations, community groups and other non-governmental organizations, all of which have opportunities for input into the CMP's implementation. By working together, the federal government and its partners are striving to meet the 2020 goal set by the World Summit on Sustainable Development for sound management of chemicals.[3]

Progress on work being carried out under the CMP is kept up-to-date at www.chemicalsubstances.gc.ca, and more detailed information about CEPA 1999 is available at www.ec.gc.ca/ceparegistry/the_act/guide04/toc.cfm. ■

Please note: Full references are available in the HTML version of this issue of the Bulletin: http://www.healthcanada.gc.ca/hpr-bulletin

Spotlight on

International Regulatory Cooperation

Brenda Czich, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada, and **Edith Lachapelle**, Policy, Communications and Regulatory Affairs Directorate, Pest Management Regulatory Agency, Health Canada

With globalization, the international trade environment has become increasingly complex. These complexities have had a significant impact on the regulatory environment. The nature of issues that affect regulatory agencies often requires cooperation between and among countries. To better understand the process of international regulatory cooperation, this article highlights some of the approaches that are being used by Health Canada.

Embracing International Regulatory Cooperation at Health Canada

The complex global nature of issues that confront regulatory agencies in countries around the world necessitates regulatory cooperation as an essential element in contributing to public health. Within this increasingly complex regulatory environment, Health Canada has embraced international regulatory cooperation (IRC) as a means of strengthening its capacity to make regulatory decisions based on the best available science. This enhances the safety of products for Canadians and improves their access to products and therapies.

Many parts of Health Canada, including the Health Products and Food Branch (HPFB) and the Pest Management Regulatory Agency (PMRA), have strong regulatory mandates in support of the health, safety and well-being of Canadians. This article draws on experiences from HPFB and PMRA to illustrate how IRC is helping Health Canada achieve its regulatory objectives by putting safety first through the timely exchange of information, leveraging international regulatory resources and achieving program efficiencies that can reduce the burden and cost for industry, thereby encouraging the marketing of products in Canada.

During the past decade, regulatory cooperation has expanded considerably between regulatory agencies in Canada and other developed countries. For example, between 1999 and 2009, HPFB increased the number of its cooperation arrangements from less than a half dozen to over 30.[1] The public health benefits arising from such arrangements were recently illustrated by the collaborative global efforts in response to the H1N1 flu pandemic. By working in cooperation with one another and with the World Health Organization (WHO), regulators from a number of countries were able to identify clinical trial requirements to ensure the safety of the vaccine and to expedite access to it. Likewise, IRC has helped the PMRA achieve internationally recognized milestones with respect to pesticide regulation.

In addition to contributing to improved health and safety standards, effective IRC can also impact trade and economic performance. A country's health and safety regulatory regime can affect its productivity, competitiveness, trade flows, and both foreign and domestic investments.[2] Given that an estimated 80% of a country's trade is affected by standards or associated technical regulations, regulatory cooperation helps to reduce non-tariff trade barriers for industry.[3] To that end, in 2007, leaders of Canada, Mexico and the United States released the

Regulatory Cooperation Framework (RCF), which seeks to improve trilateral regulatory cooperation in order to maximize trade and lower costs for North Americans while protecting health, safety and the environment.[4]

Scope of International Regulatory Cooperation

Achieving regulatory cooperation requires a strong foundation built on mutual trust established through rigorous confidence-building experiences. Approaches to IRC vary and may include many types of cooperation from information exchange and training, to work sharing, formal harmonization and standard setting activities, as well as mutual recognition agreements (MRAs). A brief look at some of these approaches sheds light on IRC.

Information exchange

Through international arrangements with partner agencies, the exchange of information provides a broader scientific and regulatory perspective on challenging issues and greater insights into the respective regulatory processes. For example, the European Medicines Agency and HPFB recently initiated a series of regularly scheduled teleconferences on oncology products under review.[5] These "real-time" international exchanges are expected to play an increasingly significant role in Canada's domestic review process.

Capacity building

Health Canada is frequently approached to share regulatory best practices and knowledge by providing training and expertise and by assisting other countries to develop their regulatory capacity. As an example, in 2008–2009, HPFB experts, in cooperation with the WHO, conducted training programs in India to strengthen its vaccine regulatory capacity. As a result, India's national regulatory authority passed WHO's pre-qualification assessment in April 2009. HPFB's contribution to such work is critical to global health security and contributes to public health safety worldwide.

Work sharing

International work sharing is a form of cooperation whereby country regulators and international and multilateral organizations collaborate in an equitable manner throughout the life cycle of a product, in order to share in either select regulatory activities or the overall workload. This sharing allows the best available information and science to inform decision making, while each country retains its sovereignty for the oversight of regulated products.

International work sharing fosters mutual understanding of regulatory systems, facilitates cooperation and allows agencies to concentrate on priority areas. Although work sharing involves information sharing as an integral component, it can also include joint training, research, standards and guidance development, as well as joint health risk assessments and parallel or joint reviews. PMRA's joint scientific reviews of industry submissions demonstrate how work-sharing arrangements can strengthen the regulatory process while also reducing the overall workload (see sidebar, next page).

International regulatory harmonization

Harmonization refers to the establishment of a common set of regulatory technical requirements by authorities from participating countries. Harmonization activities can strengthen the foundation for work-sharing opportunities among countries.

Many areas within Health Canada have made significant contributions to international regulatory harmonization. For example, HPFB has participated in the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH), since its inception in 1990. HPFB also plays a substantive role in the work of the CODEX Alimentarius Commission, which establishes international food standards. The adoption of CODEX standards by other countries, especially developing countries, is helping to improve food safety worldwide.[6] The guidance documents produced from such activities provide a common regulatory language and are becoming de facto global standards.

Harmonizing regulatory requirements to the greatest extent possible has a number of advantages. For example, it can allow manufacturers to prepare drug submission applications in a common

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Work-Sharing Case Study: A PMRA Regulatory Success[7]

In pursuing IRC, PMRA has achieved significant milestones with respect to pesticide regulation. Joint scientific reviews of industry submissions have been key to its approach. Under this process, data submitted for review are allocated among the participating countries' regulatory authorities for primary review. Once complete, the reviews are exchanged among participants so that each review can be peer-reviewed by all other participants. This broadens the peer-review pool at an international level and leverages the strengths of the available scientific expertise. The joint review process supports simultaneous evaluation of new pesticides in numerous jurisdictions (including Canada) while meeting country-specific requirements. The relatively small Canadian pesticide market benefits from such work-sharing activities because of its need to attract pesticide manufacturing to Canada.

PMRA initially worked with its U.S. pesticide regulatory counterpart, the U.S. Environmental Protection Agency, to initiate the first joint review in 1998. A prerequisite to the collaboration was a complete review of the regulatory process in both countries, which included a review of the scientific approach to human health and environmental risk assessments, hazard identification and risk management. Streamlining was achieved without jeopardizing the regulatory integrity of either regulatory body, thus maintaining the sovereignty of final regulatory decisions.

Building on this U.S.–Canada experience, the Australian Pesticides and Veterinary Medicines Authority joined the process, resulting in the first trilateral review in 2006. The success of this process led to countries from the European Union joining the review process in 2007, thereby expanding the joint review process to a truly global collaboration.

Building on this U.S.–Canada experience, the Australian Pesticides and Veterinary Medicines Authority joined the process, resulting in the first trilateral review in 2006. The success of this process led to countries from the European Union joining the review process in 2007, thereby expanding the joint review process to a truly global collaboration. By 2008, regulatory cooperation (both joint reviews and other work-sharing initiatives) had led to 78 new product registrations (including active ingredients and end-use products) being granted.

As a result of the joint reviews, newer alternative chemical formulations have also gained quicker access to both Canadian and American markets. The cooperation has also played a role in preventing the so-called "technology gap" (i.e., the difference in access to pest management tools between Canadian growers and their counterparts in other countries) from widening, a situation that has been further enhanced by the fact that the joint review program has recently evolved to include additional uses for products. As a result, manufacturers now have additional incentives to develop and bring new products to market. Sharing the review of the scientific data submitted in support of applications is expected not only to strengthen the regulatory process, but also to increase harmonization of data requirements among regulatory jurisdictions.

format, so that applications can be accepted by all participating regulatory jurisdictions. This adoption of a "common regulatory language" allows industry to save resources and reduce drug development costs while promoting "regulator to regulator" communication. All other factors being equal, these activities can promote the earlier availability of important new therapies. At the same time, it must be recognized that the process of harmonizing regulatory requirements can be lengthy, and it is likely that regulations in a given area may never be completely harmonized.

Mutual Recognition Agreements

Mutual Recognition Agreements (MRAs) allow trading partners to recognize one another's regulatory requirements as equivalent. MRAs can strengthen regulators' capacity to ensure that imported products are safe, effective and of high quality; they can also allow regulators to make better use of existing resources by reducing the duplication of regulatory effort.[8] For example, an MRA exists between Canada and the European Community for Good Manufacturing Practices (GMP) for drugs.[9] This MRA enables Health Canada to leverage the use of other countries' inspections to certify the production of a drug by a foreign manufacturer as having passed the equivalent regulatory inspections (i.e., they are in compliance with GMP). This arrangement has resulted in a significant cost savings for the HPFB Inspectorate, in lieu of foreign inspections it is not required to undertake.

The development of MRAs require confidence in the rigor of one another's regulatory processes, as well as a substantial time investment to reach an agreement and then to maintain it. Once an agreement has been signed, it may require further revisions as jurisdictional or regulatory changes arise. These are then dealt with through a formalized process agreed upon by MRA partners.

International work sharing is a form of cooperation whereby country regulators and international and multilateral organizations collaborate in an equitable manner throughout the life cycle of a product, in order to share in select regulatory activities or the overall workload.

Enabling International Regulatory Cooperation

New communication tools and technologies have been instrumental in enabling Health Canada to pursue IRC. For example, in 2004, the PMRA launched "e-PRS" (the Electronic Pesticide Regulatory System). This system has transformed pesticide regulation in Canada by allowing companies to conduct secure, web-based transactions when submitting applications, and by providing PMRA with mandatory safety data. This model has been the subject of international attention. Led by PMRA, the Organisation for Economic Co-operation and Development (OECD) is in the process of adopting Canada's e-PRS model on a global scale.

Additionally, in 2009, HPFB launched its *Natural Health Products Online Solution*, which provides a secure, world-class online system for processing natural health product submissions, site licences and clinical trial authorizations for natural health products in Canada.[10] Regulatory agencies in other countries have expressed considerable interest in this system since its development.

Moving Forward

Regulatory cooperation with key international counterparts is an essential means of responding to challenges posed by globalization, rapidly evolving science and the development of new technologies. In Canada and other developed countries, IRC is increasingly considered by many regulatory agencies to be a cornerstone in fulfilling their respective health and safety mandates.[11,12] While such activities are important for Canadian industry to remain competitive in the increasingly globalized trade environment, Health Canada will continue to exert sovereignty in its decision making to put health and safety first.

Although IRC has strengthened Health Canada's ability to address the global challenges associated with its regulatory mandate, more policy research on the benefits of international regulatory cooperation is needed to better document and quantify enhancements to public health. ■

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Looking Ahead:

The Importance of Regulatory Foresight

Linda Senzilet, Associate Editor of the Health Policy Research Bulletin, *speaks with* **David F. Clapin** *(DC), Office of Science and Risk Management, Health Products and Food Branch, Health Canada, and* **Nigel Skipper** *(NS), Science and Technology, Foresight and Science Promotion Division, Strategic Policy Branch, Health Canada.*

Q *What is "foresight" and how does Health Canada use it in its work?*

NS: Simply put, foresight involves looking "down the road" to envision what science and technology (S&T) will look like in the future. Foresight is key to Health Canada's ability to access and perform the science it needs. It also helps the Department to identify scientific developments early in their genesis, so that it can respond in a timely way. Keeping current with key trends in science will help the Department re-order its priorities and focus on accessing knowledge and expertise in those areas.

Foresight *feeds* the planning process, but is not a *part of* the planning process. For example, strategic planners look at S&T trends in developing their medium- to long-term policy agendas. People engaging in foresight, however, try to picture what S&T will look like in 20 or 30 years. This is critical because when we develop new legislation and regulations, we expect that they will be in effect for a generation.

Q *What do we mean by the term "regulatory foresight"?*

DC: New technologies and new kinds of health products are being developed all the time—some have the potential to revolutionize the treatment of certain diseases. However, because science is evolving at a faster pace than our legislation and regulations, regulatory authorities often don't have the information, tools or authorities to adequately keep pace with questions related to the health, safety and environmental impacts of products at the leading edge of technology. This is where "regulatory foresight" plays a role.

Regulatory foresight begins by looking at evolving global trends in S&T and anticipating what new types of health products are likely to come onto the market in the coming years. By doing so, regulators can "close the regulatory gap" between the current regulatory regime and what will be needed in the future to assess the safety and effectiveness of those new products. The regulator's response to evolving science and technology has to include the development of effective policies, regulatory adaptation, standards and protocols. As well, the regulator has to ensure that there are staff and systems in place to meet these new demands. A complete regulatory response to a need imposed by scientific and technological change is a complex systemic issue for government and society.

Regulatory foresight begins by looking at evolving global trends in S&T and anticipating what new types of health products are likely to come onto the market in the coming years.

Q *Are "regulatory gaps" new?*

DC: Gaps between regulatory systems and the advance of S&T are always occurring, from the small scale to the major changes with big implications. For example, advances in materials science can impose new demands on regulatory safety assessments in a short period of time. In the 1940s, developments in polymer chemistry led to "new technologies" for plastics. Until that time, many products such as medical devices (e.g., syringes) were made of metal or glass, and food was packaged in paper materials. Suddenly, many things could

be made from plastic or other composite materials. This change had huge implications for the regulation of a variety of products. For example, regulators needed to keep pace to ensure that the regulatory framework was adapted to the new requirements for evaluating sterile products, and to assess the risk that chemicals could leach from plastic containers or equipment and cause contamination.

What "regulatory gaps" are currently on Health Canada's radar?

DC: Today I would say that nanotechnology has enabled the development of new materials which are rapidly working their way through the world of design, fabrication and capabilities of products. This single area of change has the potential to affect many standards, regulations and evaluation strategies for safety and effectiveness all at once.

There are other changes operating at a more focused level within particular sectors. An example is the growth of new manufacturing technologies which combine basic laser ink jet mechanics with new substrates that are biologically active. What does that mean? It means the "printing" of solid, synthetic organs or tissues using "bio-inks" on layers built up from "bio-paper" sheets. Working prototypes of machines for bio-printing and bio-fabrication are in operation; these technologies are in the medium-term horizon. They certainly stretch the boundaries of what we normally think of with respect to organ and tissue transplantation, and the borderline of regulation driven by the concept of fabrication of conventional medical devices. Existing regulatory frameworks are robust and can accommodate, but regulatory foresight is needed to help guide that process.

Under what time horizon does regulatory foresight operate?

DC: Regulatory foresight has a range of time horizons. In the *short term*, it is concerned with immediate trends, like estimating the number of potential new drug submissions based on approvals in other jurisdictions, or "pipeline" meetings with companies—this kind of foresight is useful for operational planning, such as forecasting workloads for evaluators. In the *medium term*, regulatory foresight looks further afield to "discovery science"—the sources of information could be registries of clinical trials and publications appearing in the primary literature. For example, discoveries in stem cell research mean that new areas of commercialization will eventually open up. Regulators will need to develop a policy-driven response to such technologies by anticipating their impacts (including important social and ethical impacts) and developing a precautionary stance toward them.

Finally, in the *longer term*, there is more opportunity to be proactive and to guide the regulatory system so that it aligns as closely as possible with the predicted course of evolution of science and technology. This means that we have to be conscious of scientific and technological innovation on the far horizon. One of these is the field of synthetic biology, the technology of writing genomic sequences for the purpose of creating new kinds of living things. Although there are no immediate health applications, it is not too soon to consider what such technologies might mean for us as regulators.

What kinds of tools does Health Canada use to conduct its foresight activities?

NS: Recently, Health Canada hosted the first of three national S&T foresight workshops, at which participants from government, industry, academia and NGOs identified key S&T trends and drivers that will impact both the Department and the health of Canadians by 2030. We also discussed how Health Canada and its partners could potentially respond to these challenges and opportunities. At two other workshops that the Department will sponsor later this year, we will engage in scenario building by creating plausible scenarios, describing their potential impacts and then "stress testing" them against our current priorities to see how they might inform strategic planning and influence the policy process.

DC: The Health Products and Food Branch (HPFB) has also used scenario-building exercises. For example, when the Branch embarked on its project to look at the life-cycle approach to regulating drugs (see article on page 17), we used scenario-building techniques to explore alternative situations, ranging from rapid commercialization of significant new life-saving drugs for small populations to multiple generations of a product type with insignificant incremental gains in therapeutic outcomes. This allowed us to consider how a licence could be truly matched to the life cycles of products.

NS: Another tool that we use is hindsight! We look back about 20 years or so and think about what was going on then in S&T, and what we would have had to do in order to be where we want to be today.

DC: In conducting regulatory foresight, HPFB draws from a broad range of information sources. From the life sciences and medical literature, we can anticipate future clinical trials and drug submissions; from current clinical trial registries, we search for active areas of product development and testing. We also analyze S&T scans and regulatory approvals databases published by other countries, as well as clinical practice guidelines. These guidelines help us understand how the health products that we approve are used by clinicians, and help us anticipate new trends and developments in clinical practice. One source that is underutilized, in my opinion, is the patent literature. That would be a longer term forecasting tool, since it is needed relatively early in the product commercialization cycle.

We need a systematic and sustained commitment so that new information can be synthesized and effectively applied to policy making. Foresight has three components—analysis, engaging people and action—we need all three.

Q *What are some of the barriers to undertaking foresight activities?*

NS: Approaching foresight half-heartedly is a barrier. We need a systematic and sustained commitment so that new information can be synthesized and effectively applied to policy making. Foresight has three components—analysis, engaging people and action—we need all three. Also, because so much of science innovation occurs outside of government, we need to maintain effective linkages with innovators beyond our walls.

DC: Also, although policy development is a core departmental function, foresight activities can be prone to "displacement" by immediate and urgent priorities. As a regulator, every function we undertake is tested against the need to get our core benefit/risk evaluation job done and avoid review backlogs, as well as our ability to respond quickly to any and all emerging safety issues.

Q *Finally, what does the future of regulatory foresight look like at Health Canada?*

DC: "Encouraging Responsible Key Technologies" is a primary objective of HPFB's *Strategic Science Plan*. There are two parts to this undertaking. First, we need to maximize the benefits of existing and "horizon" technologies by monitoring cutting-edge technologies, especially when their future impacts are largely unknown. Second, as next-generation technologies become a reality, there will be new opportunities for innovation. While new manufacturing practices have the potential to create novel and higher quality therapeutic products, there is also an increased demand for lower production costs; this has resulted in some health products being produced in countries with less stringent standards. HPFB's regulators need to ensure that these imported health products are effective and safe for Canadian consumers.

NS: Speaking from the perspective of Health Canada as a whole, both the recent S&T Strategy and *Strategic Science Plan* have acknowledged the need for the Department to think systematically about the role of foresight. A new S&T Foresight Unit is championing foresight and engaging S&T communities within Health Canada and beyond. The creation of a new Virtual Centre of Expertise in Foresight is one of four short-term priorities established under the departmental Science Plan. Once the Centre becomes operational in early 2010, it will provide employees with the methods, best practices and other tools that are useful for this type of systematic thinking.

Health Canada is taking advantage of innovative information and communication technologies to set up new ways of conducting foresight activities. A good example is the recently created departmental Wiki, which allows our scientists and policy analysts to be more engaged with one another as they use information that they produce or find.

The workshops that I spoke about earlier represent the beginning of an era of systematic foresight investment by Health Canada; it is anticipated that they will provide ongoing and broadly considered insights into the most durable and effective S&T-related policies, programs and regulations.

All of these departmental activities have begun to entrench the value of deliberate and ongoing engagement related to the future impact of science and technology. These efforts will allow Health Canada to be a better prepared and more robust organization. ■

Using Canada's Health Data

Using Canada's Health Data is a regular column of the *Health Policy Research Bulletin*, highlighting some of the methods used in collecting, analyzing and understanding health data. In this issue, we look at the role of public opinion research in the regulatory process and examine a systematic approach for analyzing input from stakeholder consultations.

Public Opinion Research—What It Is and How We Use It

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Health Canada relies on accurate, up-to-date public opinion research (POR) to help it better appreciate the social and ethical nuances of scientific and regulatory issues and the impacts of policy choices on Canadian society. Results of this type of research also allow the Department to understand stakeholder and citizen needs, perceptions and expectations about health. POR can help policy and decision makers obtain knowledge that contributes to shaping policies and programs and to supporting the development of regulations and the ongoing monitoring of their effectiveness.

Canadians' views are split on the adequacy of product safety information

A 2007 study indicated that a majority of Canadians (54%) believed they currently have the right amount of information about the safety of consumer products. More than one third (37%), however, believed that they did not have enough information about product safety.[1]

Public opinion research offers the Government of Canada a "listening post" to hear clearly the opinions, attitudes and views of Canadians about a variety of issues (see sidebars). The *Communications Policy of the Government of Canada* requires that government "consult the public, listen to and take account of people's interests and concerns when establishing priorities, developing policies and planning programs and services."

POR is defined as "the planned gathering, by or for a government institution, of opinions, attitudes, perceptions, judgments, feelings, ideas, reactions or views that are intended to be used for any government purpose, whether that information is collected from persons (including employees of government institutions), businesses, institutions or other entities, through quantitative or qualitative methods, irrespective of size or cost."[3] POR can include policy research, market research, communication research, program evaluation, and quality of service and customer satisfaction studies.

How does Health Canada use POR?

Health Canada conducts POR to serve a number of purposes: to assess Canadians' awareness, knowledge, opinions and behaviours related to a particular issue in order to help shape a health policy or program; to test awareness of, and satisfaction with, a proposed initiative among a certain group of stakeholders; to evaluate the effectiveness of a program or service; and to find out what employees think of various corporate issues.

Different needs, different types of POR

Health Canada draws upon a range of POR methods, some quantitative and some qualitative. The nature of the research and its goals, the type of data needed, the timing and available budget all help to determine which techniques are selected.

Quantitative techniques are used when statistically reliable data about people's knowledge, opinions, attitudes and behaviours are required. They are the best choice when researchers wish to: gather baseline data as the basis of policy or program development; track changes in public opinion, attitudes or behaviour over time; post-test an advertising campaign; or identify client profiles. Data are collected from a sample that is selected to represent the population of interest. Surveys (in-person, telephone, mail, online) are an example of quantitative research.

Canadians view food safety as a high-priority issue

When Canadians were asked in March 2007 to rate the importance of 10 specific health issues, the top two were ensuring the safety of food products (91% total, including 61% who said "extremely important") and ensuring the safety of pharmaceutical products (90% total, 60% who said "extremely important").[2]

Qualitative techniques result in data that are more subjective than those collected through quantitative techniques. Although their results cannot be generalized to the target population,

qualitative techniques can yield valuable insights into the attitudes and views held by the population. Qualitative methods are used to: explore ideas about improving a program or service; pre-test creative concepts for an advertising campaign; test clarity, comprehension, content and format of publications; learn about a client's experience with a program or service; or generate new program or service concepts. Examples of qualitative research include focus groups and in-depth interviews (see "Analyzing the Results of Stakeholder Consultations" below).

Mad cow disease did not have a major impact on beef consumption

In 2003, three quarters of Canadians (77%) reported eating the same amount of beef as they were eating before mad cow disease was found in one cow in Alberta. Just 7% were eating less beef.[4]

Analyzing the Results of Stakeholder Consultations—An Innovative Approach

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Health Canada holds formal consultations with stakeholders on a variety of regulatory issues. Traditionally, stakeholder input has been qualitatively analyzed by parsing the material and assessing the strength and frequency of differing views. The sheer volume of information created by the increased use of stakeholder consultations has created a need for using analytical approaches that are more manageable and reliable. This article introduces the concepts and techniques associated with a systematic approach to this type of analysis.

What Is Systematic Analysis?

Systematic analysis is an approach to analyzing large amounts of stakeholder input. Not only does it improve the consistency, accuracy and fairness of the process and its results, it also saves time, especially when the volume of input exceeds a few hundred pages.

The innovation of systematic analysis of stakeholder consultations lies not in the sophistication of these methods, but rather in the new ways and contexts in which analysts at Health Canada are applying them.

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Three key steps are followed in systematic analysis:

Step 1: Carefully identifying, in advance, which questions and issues will be explicitly tracked in the consultation process. This includes the design of tools, such as questionnaires and evaluation forms, to capture the input in a format that can be analyzed systematically.

Step 2: Translating the incoming information into standardized formats and measures that lend themselves to systematic analysis and comparison. This usually involves the creation of an electronic database.

Step 3: Using tallies, or counts, to identify the relative frequency and strength of stakeholder positions. These counts can replace vague qualitative qualifiers such as "some," "many" and "most" that are used in more traditional forms of consultation analysis.

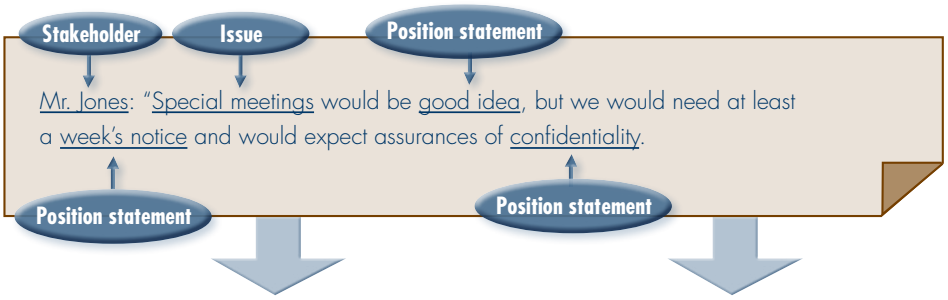
Although results of the systematic analysis of stakeholder input cannot be used to generalize about the wider population of stakeholders, they do take into consideration the diverse range of opinions and give a condensed, quantitative picture of the oral and written input received. Furthermore, they provide additional tools to make the analytical process more manageable and more reliable.

How is consultation input "translated" into data?

Two types of data emerge from stakeholder input:

- Answers to categorical questions (in which each respondent chooses one response from among a finite number of options) are tallied to provide straightforward descriptive results upon which to base conclusions.
- Complex text responses to open-ended questions (which allow stakeholders to respond entirely in their own words), as well as free-form input such as letters or speeches, are coded according to a general list of issues that are determined before the coding itself begins. Analysts read all responses to a given question, list the general issues that have emerged, and assign each one a

Figure 1 Fictional Example of Coding Stakeholder Input



Record Number	Source Document	Stakeholder Group	Issue Code	Position Statement Code (and Label)
1012	**5**	**3**	**3**	**1** (support)
1013	**5**	**3**	**3**	**18** (timing concerns)
1014	**5** (November 27 consultations transcript)	**3** (Mr. Jones, ABC Biologics)	**3** (special meetings)	**12** (confidentiality concerns)

Note: This example is based on fictitious data.

numerical code. If a particular stakeholder's response addresses more than one issue, that response may be tagged with multiple issue codes. As Figure 1 illustrates, verbal and written position statements are then transformed into individual data records. Each record identifies the source document, the group to which the individual stakeholder belongs (e.g., industry, public health), the issue addressed (e.g., whether to hold special meetings), as well as the specific position(s) taken by the respondent (each position is given a unique code). Once all data are entered, the analyst tallies the frequency of each position statement to yield, for example, the number of respondents citing timing concerns, the number citing confidentiality concerns, etc.

Analysts may present these records in tables, along with qualitative insights and representative quotations selected from the submissions.

Health Food Claims Consultations—A Successful Test Case

Systematic analysis of consultation data has been undertaken many times at Health Canada in recent years. For example, in early 2008, the Food Directorate of Health Canada's Health Products and Food Branch conducted a national consultation to consider a discussion paper on Health Claims for Food.[5] That paper outlined policy options and raised questions surrounding claims that food manufacturers make about the health benefits of their products.

The Food Directorate provided stakeholders with a questionnaire (which included both categorical and open-ended questions) to guide their written submissions. The Directorate received 71 stakeholder submissions comprising over 1,200 pages of written material. Analysts used a systematic approach to summarizing the data and presented a numerical picture of the views and opinions of stakeholders on 40 pages of text and in 25 tables.[6] The consensus among the project team was that this test case demonstrated an efficient use of resources, and that the findings greatly facilitated the Department's understanding of stakeholder views. This approach had been applied without significantly changing the well-established government consultation process, and was well accepted by the Health Canada project team, including the decision makers.

Benefits of Systematic Analysis

A systematic approach to analyzing public input can replace fallible recall and subjective impressions with more reliable, evidence-based analysis. This is especially true when the volume of input makes it difficult to form a comprehensive mental picture of the data. Systematic analysis also helps analysts to maintain their objectivity and perspective. As the benefits of systematic analysis become more evident to both decision makers and stakeholders, it is possible that this approach will be more frequently incorporated into the process of analyzing public consultations. ■

@ *Please note: Full references are available in the HTML version of this issue of the Bulletin: http://www.healthcanada.gc.ca/hpr-bulletin*

New and Noteworthy

New and Noteworthy is a regular column of the *Health Policy Research Bulletin*, highlighting recent policy research and related events in the health field.

Air Pollution and Hospitalization for Headache in Chile

Robert E. Dales and **Sabit Cakmak**, Environmental and Radiation Health Science Directorate, Healthy Environments and Consumer Safety Branch, Health Canada, and **Claudia Blanco Vidal**, Area Descontaminacion Atmosferica, Comisión Nacional del Medio Ambiente (CONAMA), Metropolitana De Santiago, Chile

Collaborating under the Canada–Chile Agreement on Environmental Cooperation, the authors performed a time-series analysis to test the association between air pollution and the daily numbers of hospitalizations for headache in seven Chilean urban centres from 2001 to 2005. Results were adjusted for the day of the week and the humidex. Three categories of headache—migraine, headache with cause specified and headache not otherwise specified—were associated with air pollution. There was no significant effect modification by age, sex or season. The authors concluded that air pollution appears to increase the risk of headache in Santiago Province. If the relation is found to be causal, the morbidity associated with headache should be considered when estimating the burden of illness and costs associated with poor air quality. This paper was published in the *American Journal of Epidemiology* in September 2009. For more information, please contact Sabit Cakmak at: sabit.cakmak@hc-sc.gc.ca

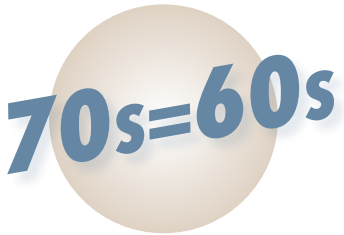
Working Conditions of Nurses and Absenteeism: Is There a Causal Relationship?

Sameer Rajbhandary and **Kisalaya Basu**, Applied Research and Analysis Directorate, Strategic Policy Branch, Health Canada

This study built on previously published descriptive analyses of the Canadian 2005 National Survey of the Work and Health of Nurses; however, it was the first to investigate the causal relationship between working conditions and illness- and injury-related absenteeism of full-time Registered Nurses and Licensed Practical Nurses. Results identified some significant causal relationships between working conditions and absenteeism, and suggested that improving working conditions would likely decrease absenteeism among these groups of nurses. This paper was presented at the *International Conference on Applied Economics* held in Kastoria, Greece, in May 2009. For more information, please contact Sameer Rajbhandary at: sameer.rajbhandary@hc-sc.gc.ca

Population Aging and Health Status in Canada: Is 70 the New 60?

David Dougherty and **Michael Scheltgen**, Applied Research and Analysis Directorate, Strategic Policy Branch, Health Canada



This study sought to determine whether the financial burden of caring for the seniors of tomorrow might be less than many predict. Using various data published from the late 1970s to the mid- to late 2000s, the authors plotted age-specific data for health status and remaining life expectancy for men and women. The authors fitted polynomial curves to the data to calculate the age at which people are now as healthy as people in their early 60s used to be. **Health status:** Results showed that age-specific health status has improved among older adults. For instance, 71-year-old men and 67-year-old women living in 2006 were as healthy as their 60-year-old counterparts living in the early 1990s had been. **Remaining life expectancy:** A 63-year-old man and a 62-year old woman living in 2006 could have expected as many remaining years of life as their 60-year-old counterparts living in 1990 could have expected. If these trends continue, baby boomers, at least in their early years of retirement, will be much healthier than the seniors of the past; all else being equal, they are likely to demand less of the health care system than did their predecessors. This paper was presented at the *Annual Conference of the Canadian Association of Health Services and Policy Research* in Calgary in May 2009. For more information, please contact Michael Scheltgen at: michael.scheltgen@hc-sc.gc.ca

Health Portfolio Sex- and Gender-Based Analysis Policy

Bureau of Women's Health and Gender Analysis, in cooperation with the Health Portfolio Sex and Gender-Based Analysis Working Group, Health Canada

In July 2009, Health Canada's Gender-Based Analysis Policy of 2000 was replaced by the Health Portfolio Sex- and Gender-Based Analysis (SGBA) Policy. The new policy was developed to better reflect the structure and needs of the federal Health Portfolio. Evidence demon-

strates that the biological, economic and social differences between men and women and between boys and girls contribute to differences in health risks, health services use, health care system interaction and overall health outcomes. SGBA is an analytical approach which integrates sex (biological) and gender (sociocultural) perspectives into the development, implementation, monitoring and evaluation of research, policies and programs. SGBA is meant to be applied within the context of a diversity framework; the use of SGBA is therefore integral to ensuring that research, programs and policies address the needs of all Canadians. For more information, please contact Jennifer Payne at: jennifer.payne@hc-sc.gc.ca ■

Mark Your Calendar

What	When
Canadian Association for Health Services and Policy Research (CAHSPR)	May 10–13, 2010 Toronto, ON **http://www.cahspr.ca/**
e-Health 2010	May 30–June 2, 2010 Vancouver, BC **http://e-healthconference.com/**
Canadian Public Health Association Centenary Conference	June 13–16, 2010 Toronto, ON **http://www.cpha.ca**
14th International Conference of Drug Regulatory Authorities	November 30–December 3, 2010 Singapore **http://www.who.int**

Health Policy Research Bulletin

The *Health Policy Research Bulletin* is normally published two times a year with the aim of strengthening the evidence base on policy issues of importance to Health Canada and the Public Health Agency of Canada (PHAC). Each issue is produced on a specific theme and, through a collaborative approach, draws together research from across Health Canada, PHAC and other partners in the federal Health Portfolio. The research is presented through a series of interrelated articles that examine the scope of the issue, provide an analysis of the impacts and potential interventions, and discuss how the findings can be applied in the policy development process.

Following is a list of all of our past issues, available in electronic HTML and PDF versions at: http://www.healthcanada.gc.ca/hpr-bulletin, or by contacting us at: bulletininfo@hc-sc.gc.ca

- **Financial Implications of Aging for the Health Care System** (March 2001)
- **The Next Frontier: Health Policy and the Human Genome** (September 2001)
- **Health Promotion—Does it Work?** (March 2002)
- **Health and the Environment: Critical Pathways** (October 2002)
- **Closing the Gaps in Aboriginal Health** (March 2003)
- **Antimicrobial Resistance: Keeping it in the Box** (June 2003)
- **Complementary and Alternative Health Care: The Other Mainstream?** (November 2003)
- **Health Human Resources: Balancing Supply and Demand** (May 2004)
- **Child Maltreatment: A Public Health Issue** (September 2004)
- **Changing Fertility Patterns: Trends and Implications** (May 2005)
- **Climate Change: Preparing for the Health Impacts** (November 2005)
- **Social Capital and Health** (September 2006)
- **The Working Conditions of Nurses: Confronting the Challenges** (February 2007)
- **People, Place and Health** (November 2007)
- **Emergency Management: Taking a Health Perspective** (April 2009)