

# SMART REGULATION REPORT ON ACTIONS AND PLANS

Fall 2005 Update



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# Message from the President of the Treasury Board

The Government of Canada committed to report twice each year on the progress of Smart Regulation initiatives. This report, aimed at both regulatory stakeholders and the public, responds to this commitment and is an important mechanism in the process of renewing our regulatory system. It also demonstrates our goal to be transparent with respect to areas of progress, as well as areas where delay has been experienced.

For our regulatory system to be effective, it must have a solid policy foundation, respond to the needs of Canadians, and be forward-thinking to address the realities we increasingly face, such as rapid scientific development, global economic challenges, and cross-boundary health, environmental and security risks. To achieve real results, that is, those that are quantifiable, we must remain committed to building a robust and adaptable regulatory system that fosters productive and co-operative relationships with partners and stakeholders, and that accounts to the citizens it serves.

In the short time since its March 2005 launch, Smart Regulation has made early strides, underscoring the federal government's commitment to moving forward on regulatory renewal and making improvements in key sectors. Federal regulatory departments are collaborating to improve coordination. We are working more closely with provinces and territories as partners toward common goals.



International partners are coming to the table as well, cooperating in areas of common interest. Meanwhile, the Government is continuing to develop mechanisms to strengthen the management of the regulatory system and to develop tools to more precisely measure progress.

The March 2005 launch of Smart Regulation was accompanied by the release of the first edition of this report, and posting of the Government's regulation website. In this edition, some 30 new initiatives are presented, along with updates on another 40 introduced last March. Evident here is progress on initiatives on which we last reported, including news of a 33-percent increase in process efficiency concerning drug approvals, and a system that allows 233 types of businesses to access federal, provincial and municipal permits from one Internet site. Being announced for the first time is a more efficient system for assessing new chemical substances that will reduce assessment periods while maintaining environmental and human health standards, as well as new legislation that will enable First Nations to work with

the Government in making regulations that address regulatory gaps for proposed on-reserve projects. In some cases, reported targets have not been met, for example, in the area of biotechnology, where the complexity of designing a strengthened regulatory framework, in which multiple participants are involved has led to a delay, but this will not deter us from our commitment to moving forward.

The Government is committed to a regulatory system that secures the safety, health, environmental, and economic well-being of all Canadians. This means making Smart Regulation part of the day-to-day business of government, being realistic about the time it takes to address complex regulatory issues and achieving our crucial goal of making regulatory change relevant and responsive to the needs of Canadians. The ongoing involvement of citizens and stakeholders is key to achieving success in reforming our regulatory system and creating smart regulations.



Reg Alcock, P.C., M.P.

President of the Treasury Board and Minister responsible for the Canadian Wheat Board

# 1. Why This Report?

This report is the second in a series of regular updates on Smart Regulation initiatives currently underway or planned. It is one way that the Government of Canada reports to Canadians, and supports our commitment to be accountable for this important and far-reaching initiative.

The following pages provide information about how progress is being made on regulatory renewal in Canada. The report describes plans for improving regulatory management throughout the federal government, current and planned activities in the critical area of regulatory cooperation and coordination, and the role of citizens and stakeholders in helping to shape regulatory reform.

The tables at the back of the report highlight specific regulatory initiatives undertaken by various departments and agencies that support the Government's regulatory goals and address stakeholder concerns. These tables summarize progress made on initiatives described in the first *Report on Actions and Plans* (published in March 2005), and also include new initiatives that have emerged during the past six months.

You may view this report and other news on Smart Regulation by visiting **www.regulation.gc.ca**.

### **Contact Us**

We welcome your comments on this report and how we can make it more useful to you.

Please call **(613) 943-5076** for information, or send your comments or questions to **info@regulation.gc.ca** or

1100-155 Queen Street, Ottawa, Ontario K1P 6L1.

# 2. Smart Regulation Today

Smart Regulation is a government-wide initiative aimed at improving the Government of Canada's regulatory system so that it can keep pace with today's realities and our evolving needs. It strives for a better coordinated, more transparent system that remains forward-thinking, progressive, and accountable to the citizens it serves.

Smart Regulation involves a series of projects that strengthen the policies, processes, tools and communities needed to sustain high levels of regulatory performance and facilitate continuous improvement. Smart Regulation emphasizes the importance of safeguarding the health and safety of Canadians, contributing to a healthy environment, and securing the conditions for an innovative and prosperous economy.

### **Smart Regulation: Eye on Results**

### **Improving Drug Performance**

As a result of the Therapeutic Access Strategy, the review backlog of pharmaceuticals has been eliminated and review times substantially improved. Between January and September 2005, 58 percent of submissions were reviewed within time targets, compared with 25 percent in 2004 and 13 percent in 2003. Health Canada expects to reach the international threshold (90 percent) by March 2006.

# **Principles**

Smart Regulation is based on a set of clearly defined principles:

- *Protecting the public interest:* Smart Regulation strives to find the right blend of policy instruments to achieve the greatest overall benefit to Canadians, recognizing that social, environmental, and economic objectives are mutually supporting.
- Extending the values of Canadian democracy: Decision making on regulatory matters is conducted in an open and transparent manner, with the government communicating intended results and being accountable for outcomes.
- Leveraging the best knowledge in Canada and worldwide:
   Smart Regulation recognizes that knowledge and evidence form the basis of regulation, and strives to maximize a diversity of knowledge sources and perspectives. Co-operation within Canada and internationally to share knowledge will be maximized.
- Promoting effective co-operation, partnerships, and processes: Smart Regulation strengthens co-operation with all levels of government and improves policy coherence, timeliness, efficiency, and effectiveness. It engages stakeholders, and fosters international co-operation to improve economic competitiveness.

## **Objectives**

The federal government is working toward achieving the following strategic objectives of Smart Regulation:

- Enhanced coordination across the federal government and better co-operation with other governments in Canada and internationally to help set and meet national objectives that promote social, environmental and economic well-being and improve the quality of life of Canadians;
- Increased policy coherence and the integration of social, economic and environmental principles and objectives into all stages of policy, regulation and decision making;
- Improved transparency, efficiency, timeliness and predictability of regulatory and decision-making processes, and reduced administrative burden for businesses and citizens;
- Strengthened planning and priority setting and more proactive and timely problem and risk identification to facilitate responsive regulation and to better protect the public interest;
- Improved identification, management and mitigation of aggregate and unintended impacts on areas and sectors through greater use of longer-term, integrated and whole-of-government approaches to regulation; and
- Strengthened regulatory management from design to implementation and evaluation of regulation for the continuous improvement and ongoing renewal of regulation across government.

### Smart Regulation: Eye on Results

Reform of Canada's Insolvency System

This initiative will facilitate more efficient processing of the more than 100 000 bankruptcies each year (less court time, more transparency, greater use of electronic filing and electronic communications), while putting in place mechanisms to allow more businesses to restructure to avoid bankruptcy, thereby protecting jobs. It will also provide better protection for workers in bankruptcy by giving higher priority to wage claims.

# Status of Implementation

Six months after the launch of Smart Regulation, the implementation of initiatives along three streams is well underway. The first two streams are aimed at establishing a strong foundation for Smart Regulation initiatives; the third focuses on the specifics of those departmental initiatives that will lead to a smarter approach to regulation. The three streams of Smart Regulation are as follows:

- 1. Strengthening regulatory management: A series of initiatives aimed at strengthening the policy and analytical requirements of regulation, along with the capacity to manage regulation through its life cycle, from development to implementation to review.
- 2. Enhancing regulatory co-operation: Initiatives aimed at achieving greater collaboration and co-operation within the federal regulatory community, across jurisdictions within Canada and internationally.

3. Achieving results in key sectors and thematic areas: Initiatives described in this report that are being undertaken by regulatory departments and agencies within five thematic areas that meet government priorities and serve the interests of Canadians.

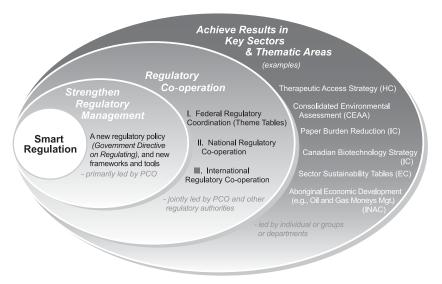


Figure 1: Concurrent areas of work

This semi-annual report allows the Government to detail progress on our commitments, while also reporting on areas where progress is slower than expected. While the majority of initiatives have met their targets, some have not moved as quickly, underscoring the complexity of issues, diversity of views, and obstacles being faced by key sectors and participants. Issues that challenge regulatory planners include confidentiality of information, legacy protocols with respect to sharing of information, sector-specific industry needs, emergency matters that shift priorities, and tendencies toward traditional practices. The sheer complexity of these issues has a significant influence on regulatory reform, and must be addressed in order for us to meet Smart Regulation goals.

However, by reporting both on areas where results are obvious and those in which progress is slower than expected, the Government is meeting its commitment to keep Canadians informed, make our regulatory system more transparent, and meet stated objectives through collaborative efforts in which all Canadians are involved.

### **Smart Regulation: Eye on Results**

#### **Reducing Paperwork Burden**

The Paperwork Burden Reduction Initiative involves measuring the cost and impact of regulatory compliance on small businesses. A public/private sector Advisory Committee on Paperwork Burden Reduction was created in March 2005 and, as scheduled, has held three meetings to date. This committee, which is developing a list of concrete recommendations to simplify requirements, will present its first progress report in December 2005.

# **How Canadians Are Participating**

In keeping with the principle that decision making on regulatory matters be conducted in an open and transparent manner, the federal government has developed a Consultation and Engagement Strategy. The strategy outlines opportunities for Canadians, whether members of the public, industry, academia, Aboriginal organizations or public advocacy groups, to help shape a new regulatory approach and to ensure that it is fair, relevant and effective.

The Consultation and Engagement Strategy describes mechanisms that will be employed to engage Canadians, including the following:

- Web-based information exchange: The Government's official site on regulation, www.regulation.gc.ca, provides the public with comprehensive and up-to-date information about Smart Regulation. An online form is available on the site that enables interested parties to submit comments electronically. Interested parties will be e-mailed whenever substantive new information is available for review.
- Reference Group on Regulating: This group met for the first time in July 2005 and again in September 2005. Comprised of people who represent a broad spectrum of interests, this group is mandated with providing an external perspective on the Government Directive on Regulating as it evolves, as well as on related documents, such as the International Regulatory Cooperation Framework, Proposal for Regulatory Review, Regulatory Learning and Community Building Strategy, and Risk Management Framework. The Reference Group will meet again at the end of this year.
- *Cross-Canada workshops:* A series of workshops will be held in November 2005 in selected locations across Canada. These workshops will provide participants with an opportunity to discuss their views on the draft *Government Directive on Regulating*.

Other mechanisms include federal interdepartmental consultations and a federal-provincial/territorial working group aimed at ensuring that federal departments and other levels of government are able to provide input to the Smart Regulation agenda. International agencies will be consulted as well, to share lessons learned and best practices on regulatory renewal.

A Regulation Advisory Board will be created in 2006 to provide an ongoing forum for stakeholder participation in regulatory management and external oversight of the Government's progress in transforming the regulatory system. The Board may also examine sector-specific issues where regulatory gaps exist.

New efforts are being made by departments and agencies to involve stakeholders in the regulatory process, particularly during the development stages. For example, the Government's Sector Sustainability Tables will bring together government, industry, labour, Aboriginal peoples and non-governmental organizations to provide informed advice on how to improve the level of environmental performance in a way that strengthens the long-term competitiveness of the sectors involved. Health Canada is working to enhance the transparency of its regulatory decision-making system by involving stakeholders in task forces as well as in public hearings, such as the recent ones on COX-2 inhibitors and silicone gel-filled breast implants.

### Smart Regulation: Eye on Results

### **Sector Sustainability Tables**

Four sector-specific (forestry, mining, energy, chemicals) tables, as well as one dealing with crosscutting issues, have been created to bring together governments, industry, labour, Aboriginal peoples and non-governmental organizations to provide advice on how to improve environmental performance in a way that supports the long-term competitiveness of the sectors involved. The goal is to promote better environmental policies and decisions by engaging stakeholders in discussion.

# 3. Strengthening Regulatory Management

The first *Report on Actions and Plans* provided information on a series of initiatives led by the Privy Council Office (PCO), aimed at strengthening the Government's regulatory management capacity. In particular, we reported on a series of initiatives under the umbrella of "Developing a New Management System for the Development and Implementation of Regulation." This multi-stakeholder process was designed to support a revised Government of Canada regulatory policy and a life-cycle approach that accommodates all stages of regulation—from development through implementation to review.

Canada's regulatory management system is the cornerstone of Smart Regulation. It creates the basis on which rules that affect the lives and interests of all Canadians can be established. It also accommodates a more dynamic approach to managing regulation, with a greater emphasis on performance, cost-effectiveness, timeliness, flexibility and continuous improvement, resulting in a regulatory culture that is open, inclusive and accountable to Canadians.

What follows is an update on these initiatives as well as new ones that have been undertaken in recent months since the launch.

## **Update on Existing Initiatives**

### Government Directive on Regulating

Among the priorities identified in the first *Report on Actions* and *Plans* is the need to review and amend the existing regulatory policy, a policy that was first implemented in 1986 and updated in 1999. Considerable progress has been made toward developing the new policy, which is called the *Government Directive on Regulating*, as well as the tools and processes necessary to strengthen regulatory governance.

The Government Directive on Regulating is designed to

- communicate to Canadians the Government's commitment to protect health and safety and to provide supportive conditions for an innovative economy;
- ensure that Canadians have information and opportunities to participate in regulating;
- communicate to government officials their regulatory roles and responsibilities; and
- ensure that ministers have the information necessary to make sound decisions.

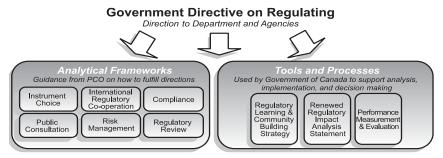


Figure 2: A new policy, supported by frameworks and tools to strengthen regulatory management

Development of the directive is important for all Canadians because it is the basis upon which we will bring about a culture change in the way that we regulate. It will make the regulatory system more transparent and accountable, providing stakeholders with the opportunity for greater involvement and input throughout the regulatory life cycle. It will allow us to monitor performance and make adjustments when necessary, enabling continuous improvement. Development of the directive also involves a broad-based consultation and engagement process with interested parties.

The *Government Directive on Regulating*, which will be completed by March 2006, will establish a life-cycle approach to regulatory governance by identifying requirements for regulatory management, impact analysis, and reporting results to Canadians. It will also provide an opportunity to integrate modern policy and management techniques into the regulatory system. The development of most tools and processes to support the new system will also be completed by March 2006, with a planned focus in 2006–2007 on implementation.

Since the March edition of this report, the following progress has been made:

- Guiding principles and strategic objectives have been developed. These are available at www.regulation.gc.ca.
- A draft of the directive has been prepared, also available at www.regulation.gc.ca.
- A Consultation and Engagement Strategy is being implemented that includes public workshops in various cities across Canada in November and provincial/territorial consultation.

### Smart Regulation: Eye on Results

#### **Economic Development on Reserves**

The proposed *First Nations Commercial and Industrial*Development Act will enable the federal government, at the request of First Nations, to make regulations on environmental protection and health and safety to support major on-reserve commercial or industrial development. This initiative underscores Canada's commitment to work with First Nations to build the tools for economic development, and will create a level playing field with similar off-reserve projects regulated in part by provinces. The proposed legislation will be introduced in fall 2005.

# Framework for Assessing, Selecting and Implementing Instruments for Government Action

Many instruments for government action exist to support the advancement of public policy. Choosing an instrument, or an appropriate mix of instruments, involves selecting those tools that will be most effective in achieving public policy objectives on a sustained basis and at an acceptable cost. The Instrument Choice Framework will assist in selecting appropriate instruments for government action (e.g., laws, regulation, taxation, standards, publications and education) to provide guidance to federal departments and to increase consistency in the analytical work that feeds the decision-making process. Work on the Instrument Choice Framework has been completed and it is now available for use by officials.

### Guide for Effective Regulatory Consultations

The Guide for Effective Regulatory Consultations assists departmental officials in designing a clear and inclusive consultation plan during the development of regulatory proposals. It covers topics such as ensuring clarity of purpose and objectives; coordination of regulatory consultation across departments; conducting internal and external scans; choosing the right tools; developing realistic timelines; and evaluating the process. The Guide for Effective Regulatory Consultations is available at www.regulation.gc.ca.

### Smart Regulation: Eye on Results

#### BizPal

BizPal is a web-based service that allows businesses to generate a customized list of the permits and licences required by all levels of government, saving both time and money. For example, an entrepreneur in Kamloops will be able to generate a customized list of the 12 permits and licences required to open a restaurant, the order in which they must be obtained, contact information and, in some cases, expected processing times. The pilot project, launched in October 2005, includes Industry Canada, Ontario, British Columbia, Yukon, and several municipalities. To date, the process of getting permits and licences for 233 types of businesses has been mapped.

### Framework for the Triage of Regulatory Submissions

This framework ensures that federal regulatory proposals are treated according to their relative importance through a consistent, open and transparent process. It provides for an abridged Regulatory Impact Analysis Statement (RIAS) for proposals of low significance. For proposals of higher significance, the framework helps departments and agencies identify and explain areas where the greatest regulatory impact is expected. The framework is guided by the principle of proportionality. Given that the government must use public resources as efficiently as possible, analytical efforts dedicated to regulatory proposals should be commensurate to their level of expected impact on Canadians.

The framework is a work in progress and involves a collaborative effort among departments, agencies and the PCO. Use of the framework will be closely monitored as it is implemented in fall 2005. A review will take place one year after implementation.

### Regulatory Learning and **Community Building Strategy**

This strategy is aimed at strengthening the capacity of those charged with carrying out the Government's regulatory responsibilities. The key objectives are to further build a professional regulatory community, advance horizontal approaches to regulating at all levels of government, develop a learning strategy that addresses the needs of regulators throughout the life cycle of the process, and foster a culture of continuous learning.

The following activities have taken place since the March 2005 launch: establishment of a Project Steering Committee and Regulatory Learning Strategy Working Group to guide the development of the strategy; development of a model that provides an overview of functions carried out in support of regulatory activities across departments; focus groups to assess needs at both the national and regional levels; preliminary work on the development of competency profiles; and a proposed learning curriculum for the regulatory community. Implementation, which is coordinated jointly by the PCO and the Canada School of Public Service (CSPS), is scheduled to begin in April 2006.

PCO is working in co-operation with the Community of Federal Regulators Secretariat to renew this initiative and seek opportunities to address capacity issues within the regulatory community. As part of this renewal, a deputy minister was appointed as champion.

### Regulatory Data Development and **Analytical Practices Project**

There is currently little systematic data collected on regulatory activity in the Government of Canada. This project will provide accurate information on the scope of federal activity on regulation. It will result in a knowledge base on regulation for ministers, parliamentarians, government officials, and citizens. The goal of this project is to enable better assessment of the impact of regulation on the welfare of Canadians, strengthen research and policy development, and contribute to increased accountability.

Progress over the past six months includes completion of a review of existing data sources, development of a methodology to estimate regulatory activity, and completion of the first phase of data collection.

A comparative assessment is progressing on how other countries gather data on regulatory activity. A conceptual framework will be completed this fall, which will help to develop the regulatory knowledge base over the long term. A status report on regulatory data collection will be available in November at www.regulation.gc.ca.

### Smart Regulation: Eye on Results

Implementing a Canadian Biotechnology Strategy

The regulation of biotechnology presents many challenges, including the fast pace of scientific change that crosses conventional lines of regulatory authority. The Canadian Biotechnology Strategy will include a policy framework and action plan aimed at improving the regulation of biotechnology and enhancing the capacity of regulators to more quickly respond to biotechnology innovations, for example in health and agriculture, that can benefit Canadians. While progress has been made in some areas, such as aquatic biotechnology, the complexity of biotechnology and the involvement of multiple regulators in the process of designing a strengthened regulatory framework has led to a delay in delivering on March 2005 commitments. The priority for fall 2005 is developing a policy framework for novel biotechnology products.

### **Measuring Regulatory Performance**

The Government is developing an *Umbrella Results-based* Management and Accountability Framework (RMAF) as a mechanism for ongoing performance measurement and evaluation of Smart Regulation implementation. The framework, to be completed in November 2005, will be an important tool to demonstrate accountability and transparency as Smart Regulation initiatives are implemented.

The framework will use a logic model to measure the impact of the Smart Regulation initiative according to key outputs and immediate, intermediate, and ultimate outcomes. It will include an evaluation strategy to measure the extent to which intended outcomes have been achieved and the degree to which Smart Regulation principles contributed to these outcomes. It will also include data collection methods and sources, and a reporting strategy for collecting and coordinating the flow of performance data. The framework will be available at www.regulation.gc.ca.

## Smart Regulation: Eye on Results

Health Claims for Food

A new regulatory framework for product-specific health claims for foods will set out conditions for issuing certain types of health claims (e.g., helps reduce heart disease) on food labels and in advertising. It will also allow food manufacturers to deliver messages about the health benefits of their products. The framework will protect consumers from unsubstantiated claims and enable them to make informed choices when choosing food products.

### **New Initiatives**

### **Regulatory Review**

As part of the new life-cycle approach to regulating and its focus on continuous improvement, a proposed framework for regulatory review has been developed to ensure that regulations are achieving their intended results in a sustainable way. The proposed framework includes guidance on evaluation criteria and review mechanisms to be used, and provides a filter through which departments and agencies can assess their regulations in relation to good governance criteria, both when the regulation is introduced and periodically throughout its life span.

This initiative began in June with a pilot project with the Canadian Food Inspection Agency in two areas: Seeds Variety Registration; and Streamlining of Seeds Regulations and Ethical Trading of Fresh Fruits and Vegetables. The pilots will serve to identify cost estimates and appropriate ways to move forward with a broader review.

Departments have been asked to identify other specific regulations or sectors that could benefit from a regulatory review and a proposal for a broader review initiative will be developed in 2006.

Expected benefits include the following:

• For citizens: Trust that regulation is clear and accessible, and that it is more effective and relevant to safeguarding health, safety, and the environment, in keeping with social, ethical, and economic values.

- For industry: Reduced compliance costs; support for innovation and productivity.
- For government: Reduced overlap and duplication with provinces and territories; compliance and enforcement focused on high priorities; enhanced relations with citizens and industry; lower administration costs; and an evidence base for additional resources to address identified regulatory gaps.

### Framework for Developing Integrated **Compliance Strategies and Plans**

This framework will provide guidance to federal departments to improve consistency in analytical work by taking into account issues relating to compliance strategies and plans early in the policy development process. Departments will be able to more effectively evaluate risk of non-compliance with regulation and have a better understanding of the tools available to respond to variables that affect compliance.

Anticipated benefits include greater transparency in how compliance strategies and plans are designed, a more consistent approach on the use of compliance tools, and greater trust from citizens and industry in the Government's ability to ensure compliance. The framework will be completed in March 2006.

## Regulatory Risk Management Framework

This framework will outline uniform government-wide guiding principles for developing, assessing and managing regulatory response to public risk. It will also encourage improved response to horizontal risk issues that affect

multiple departments or agencies. An interdepartmental working group will provide a risk perspective on related Smart Regulation initiatives, such as the Government Directive on Regulating and other supporting frameworks. The approach and draft principles for consultation on the framework will be developed by spring 2006.

In a related initiative introduced in the March edition of this report, Health Canada has completed a dynamic risk analysis pilot aimed at integrating the analysis of risk factors into the regulatory impact analysis statement. The analysis, which was used for a regulatory proposal on consent under section 8 of the Assisted Human Reproduction Act, estimates the level of risk associated with the lack of written informed consent for the use of gametes and in vitro embryos and how this risk level would change over time with or without regulations. The risk analysis was published as part of the Regulatory Impact Analysis Statement for the proposed regulations in the Canada Gazette, Part 1 in September 2005.

### Smart Regulation: Eye on Results

### Consolidating Federal Environmental Assessments

Consolidation of the federal environmental assessment process will improve consistency and timeliness through more focused accountability and improved coordination. Consultations were held in August and September 2005 on options for a new model in which the Canadian Environmental Assessment Agency would take a greater role in the assessment of projects. At the request of industry associations, environmental groups and others, consultations will continue in order to better define, by spring 2006, effective and viable models. Other improvements will be implemented concurrent with development of the new model.

# 4. Update on Coordination and Co-operation

### Interdepartmental Coordination and Theme Table Activities

Among the first steps toward improved coordination and co-operation is getting the federal house in order. Smart Regulation encourages policy coherence among departments and promotes regulatory development using a whole-of-government approach. Few regulatory issues fall under the exclusive mandate of a single department. Horizontal management is key to developing regulatory proposals that advance government-wide social, environmental and economic priorities.

Smart Regulation theme tables help to improve coordination among regulatory departments and agencies by facilitating interdepartmental discussion early in the policy development process. Theme tables also improve transparency by providing stakeholders with an access point to the Government on issues that transcend the mandates of individual departments, and where no suitable forum currently exists.

The role of Smart Regulation theme tables is as follows:

- Identifying, reviewing, and coordinating initiatives to support Smart Regulation's agenda.
- Producing work plans and identifying specific deliverables.
- Generating interest in Smart Regulation, mobilizing expertise, building capacity, and fostering co-operation.

- Sharing best practices, successes and challenges on regulatory policy issues across departments and agencies to support continuous improvement.
- Providing a mechanism whereby stakeholder input on crosscutting issues affecting the strength and continuity of Canada's regulatory system is addressed through open discussion, co-operation, and action.

A plenary session in April 2005 provided an opportunity for the five Theme Tables to collectively discuss their mandate and to begin developing work plans. This effort resulted in the mandate statement: "Theme tables have been mandated to improve coordination among federal government departments in order to achieve and sustain high levels of regulatory performance, facilitate stakeholder input, and foster continuous improvement."

### Smart Regulation: Eye on Results

Ensuring the Safety of In-Vehicle Technology Devices

Driver distraction accounts for more than 75 percent of crashes. In order to protect Canadians from the risk of distraction from new in-vehicle telematics (e.g., navigation and entertainment systems), Transport Canada is working with auto manufacturers to develop a Memorandum of Understanding (MOU) on the safety of these devices. The selected approach takes into account the potential for product design changes in a rapidly evolving industry. While fall 2005 was the target for signing, industry concerns over the inclusion of a safety management system in the MOU has led to multiple drafts and delay.

An assistant deputy minister (ADM) "champion" has been identified for each theme table.

- Healthy Canada: Ian Shugart, Health Canada
- Environmental Sustainability: Sue Kirby, Fisheries and Oceans
- Safety and Security: Marc Grégoire, Transport Canada
- Innovation, Productivity, Business Environment: Neil Yeates, Industry Canada
- Aboriginal Prosperity and Northern Development: Warren Johnson, Indian and Northern Affairs

These senior government officials will provide strategic leadership, promote the work of the theme table, and encourage active participation among relevant departments and agencies. The ADM will report to the ADM Group on Smart Regulation on the respective progress of theme table work plans.

### **Healthy Canada**

This theme table is working to identify issues that will contribute to the health and well-being of Canadians. How and whether ethical and social considerations can be integrated into regulatory decision making is one such issue.

The theme table is currently carrying out a survey of government officials to gather information on this issue. The analysis of the survey results may contribute to informing the development of tools and practices that support the implementation of the new Government Directive on Regulating.

The theme table has also initiated discussions about developing a Smart Regulation "lens," including a core set of best practices, such as improved use of information from other regulators and increased openness and transparency, that could be applied to regulatory frameworks affecting the health and safety of Canadians. The theme table also considered the need for improvements to the regulatory process for product-specific health claims labelling for foods. Health Canada has committed to developing a new regulatory framework that will allow manufacturers to include messages about the health benefits of their products on food labels and in advertising (see description in Section 6, "New Departmental Initiatives").

### Smart Regulation: Eye on Results

Improving Aviation Safety and Security

New safety management system regulations will govern the framework for integrating safety considerations into decision making and promote a culture of risk management in aviation organizations. The first series of regulations came into effect in May 2005. A second set, under development, will apply to airports, air navigation services and flight training units. Under the Security and Prosperity Partnership, a comprehensive North American approach to strengthening aviation security will be followed. It will involve developing comparable standards for screening of passengers, hold baggage and cargo.

### Innovation, Productivity and Business Environment

Regulation underpins the operation of the market through property rights, commercial contract and competition law, and an array of administrative laws that require individuals and businesses to obtain licences and permits. Regulation must also be designed to achieve desired economic and social policy objectives while minimizing costs that hinder productivity.

This theme table will be focused on finding ways to enhance the innovation, productivity and business environment while effectively meeting social objectives. A report is under development on the impact of regulation on innovation, productivity and business, and when and how such impact should be addressed during the regulatory development/revision process. The report will examine issues based on characteristics of the regulated sector and provide information to help meet regulatory analysis requirements under the Government Directive on Regulating. A draft was completed in fall 2005 and will be discussed at an expert symposium in early 2006.

### Smart Regulation: Eye on Results

Making Therapeutic Products Safer and the Process More Transparent

Measures have been launched to strengthen the safety of therapeutic products and to enhance transparency in regulatory decisions. Two new regional adverse drug reaction centres were established in April 2005, while hearings on COX-2 inhibitors the first public forum on drug safety-were held in June. A new website, MedEffect Canada (see www.hc-sc.gc.ca) was launched in August to increase public access to product safety information and enable the timely filing of adverse reaction reports.

### Safety and Security

This theme table works to improve coordination among federal departments in order to achieve and sustain high levels of regulatory performance, engage stakeholder views and foster continuous improvement. The issues examined involve many departments and span multiple jurisdictions, including transportation safety, emergency preparedness, border security, and national critical infrastructure (NCI) protection.

Work is underway on an inventory of regulatory initiatives across departments and agencies involved in regulating activities with a safety or security link. Over the coming year, safety and security concerns being addressed through regulatory actions will be compiled, along with the nature and rationale for such actions, best practices being applied, and relevant legislative and mandate considerations at both the federal and provincial/territorial levels. This information will be used as a primer for the safety and security community on issues and best practices, and will encourage greater horizontal communication on regulatory initiatives.

### **Environmental Sustainability**

This theme table is focused on developing a common approach to regulation to support a rich and sustainable natural environment for Canadians. Its work is structured so that environmental, social and economic objectives can be achieved simultaneously.

Table members are examining issues such as identifying regulatory roadblocks, values and approaches that support regulatory culture change, and implementing a triage approach to regulation, and exchanging information on best practices. They are also exploring linkages between triage, regulatory risk, the precautionary principle, and values and ethics. Participants are considering how the table can contribute to crosscutting regulatory reviews most effectively. It will also examine marketbased instruments to select areas for further analysis.

### **Aboriginal Prosperity** and Northern Development

This theme table is primarily focused on information sharing, updates on regulatory and legislative initiatives, identifying priority areas for collaboration, and proposing new initiatives. Three themes have emerged for which the table serves as an interdepartmental link: jurisdictional issues with respect to environmental assessment and protection, both on reserves and in the North; the legislative and regulatory framework on reserves in support of economic opportunities; and regulatory policy and design for inclusion in land claim and self-government negotiations and treaty implementation. As well, the table will be an advocate to address issues such as the development of a long-term horizontal regulatory co-operation framework for the North, based on the example of the Mackenzie Pipeline Co-operation Plan.

As well, the table will contribute to the development of a federal policy and guidance on regulating on-reserve lands. It will also strive to ensure that new initiatives that result from an onreserve legislative and regulatory review in support of economic opportunities or the Northern Strategy are undertaken in a consistent and strategic manner in accordance with the principles of Smart Regulation.

# Federal-Provincial/Territorial Co-operation

As reported in the March 2005 edition of this report, the Federal, Provincial and Territorial (FPT) Working Group on Regulatory Reform was created as a forum for building the foundation for a shared approach to managing regulation. This group is co-chaired by British Columbia and the Government of Canada. Work includes developing common regulatory principles, instituting a consistent approach to regulatory impact analysis, and sharing best practices. This work will enhance the capacity of all governments to improve the effectiveness and efficiency of their regulations, and encourage regulatory co-operation across jurisdictions. Meetings were held in March and October 2005.

### Smart Regulation: Eye on Results

**Environmental Impacts of a Northern Gas Pipeline** 

A Co-operation Plan for the Environmental Impact Assessment and Regulatory Review of a Northern Gas Pipeline Project will result in a streamlined and simpler review process for the Mackenzie Gas Project. The plan, which is key to the construction of the pipeline, brings together 14 environmental assessment and regulatory authorities in the Northwest Territories. A detailed review of the Environmental Impact Statement submitted in October 2004 is underway. The project proponents have been working diligently with stakeholders to resolve issues in advance of public hearings. A decision will be made in November 2005 as to whether the hearings will proceed.

## International Co-operation

### Security and Prosperity Partnership of North America

Since the last edition of this report, Prime Minister Martin, US President Bush and Mexico's President Fox announced the new Security and Prosperity Partnership (SPP) of North America. Announced in Texas on March 23, 2005, the SPP sets out an ambitious agenda for improved North American co-operation across a range of sectors.

In June 2005, lead ministers from the three countries released work plans for close to 100 initiatives to be implemented by trilateral working groups in the next 24–36 months and on an ongoing basis thereafter. These initiatives, many of which are regulatory in nature, cover sectors such as manufacturing, transport, food and agriculture safety, border security, air security, and financial services. A commitment was made to provide progress updates every six months.

### Planned initiatives include the following:

- Establishing the Automotive Partnership Council of North America as a mechanism for North American governments to work with interested stakeholders to ensure competitiveness of the automotive sector and address a range of issues, including regulation.
- Implementing a mutual recognition agreement for telecommunications equipment to reduce the costs of duplicative testing and conformity assessments, while ensuring high standards.

- Establishing equivalent approaches to aviation security in North America, including comparable safety standards for passenger, cargo and baggage screening.
- Pursuing a mutually acceptable approach for Canada and the United States to share a single notification assessment for introducing new chemical substances, and working co-operatively within the Organisation for Economic Co-operation and Development (OECD) New Chemical Task Force to increase mutual understanding and acceptance of hazard and risk assessment for new substances.
- Developing a trilateral regulatory co-operation framework, to be finalized by 2007, to encourage regulatory co-operation and compatibility, and a reduction in redundant testing and certification, while maintaining high standards for health and safety. A seminar will be held next spring to better understand the regulatory systems of the three countries and determine ways of enhancing co-operation.

### Smart Regulation: Eye on Results

First Nations Management over Oil and Gas

Bill C-54 will allow First Nations to assume direct control over oil and gas resources on on-reserve lands and assume control over moneys held for them in the Consolidated Revenue Fund under the Indian Act. This proposed self-government legislative initiative has been developed over the past decade with First Nations that have significant oil and gas reserves on their lands. The Bill was introduced in the House of Commons in June 2005, completed second reading on October 6, and is awaiting committee approval.

### Framework on **International Regulatory Co-operation**

The Framework on International Regulatory Co-operation will provide guidance to federal departments and agencies for implementing the regulatory co-operation requirements of the Government Directive on Regulating, identifying appropriate partners for co-operation, respecting international obligations, and determining the appropriate types of international engagement.

The framework will assist departments in developing strategies to manage transboundary risks to Canadians and reduce unnecessary regulatory differences with our major partners. It will also encourage the sharing and use of best practices internationally, and the efficiency of regulatory development, implementation and enforcement.

An interdepartmental meeting involving 17 departments and agencies was held in April 2005 to discuss the framework's principles, objectives and desired outcomes. Interdepartmental and external consultations on a draft will take place in fall/winter 2005. Completion is scheduled for March 2006. This initiative is co-led by the PCO and International Trade Canada.

The Policy Research Initiative has commissioned research papers to draw lessons and identify opportunities for regulatory co-operation from Canadian and international experiences. These papers will be discussed at an expert symposium in December 2005 that will feature senior officials and academics from Canada, the United States, Mexico, the European Union, New Zealand and Australia. This process will inform both the framework and the Government Directive on Regulating.

### Smart Regulation: Eye on Results

**Assessing New Chemical Substances** 

New regulations, developed using a consensus approach among federal government, industry and public advocacy groups, create a simpler, lower cost system for assessing new chemical substances entering the market, while continuing to ensure stringent environmental and human health standards. The regulations will significantly reduce assessment periods for certain types of substances. As well, an OECD pilot project led by Canada is testing a parallel notification process aimed at simplifying and streamlining access to multiple markets for new chemicals.

# Canada-EU Framework on **Regulatory Co-operation**

Adopted in December 2004, the objectives of the Framework are to advance bilateral co-operation between regulators and policy makers, so as to facilitate trade and investment, and promote competitiveness and innovation. The first meeting of the Canada-EU Regulatory Co-operation Committee took place in May 2005, providing the opportunity for both sides to become familiar with each other's regulatory approaches. The meeting also involved looking at each country's approaches in specific areas, including consumer product safety, cosmetics and personal care products, radiationemitting devices, chemical contaminants in food, and food labelling, thereby helping to build a foundation for increased working level co-operation. It is anticipated that the next meeting will take place late in 2005.



5. Update on Departmental Initiatives

Initiative	Lead and Participants	Progress Update and Next Steps
MOU Relating to Amendments to Schedule F and Table II in Division 15, Part B of the Food and Drug Regulations:  Signing of the Memorandum of Understanding (MOU) in February 2005 initiated a 30-month pilot to streamline the pre-publication (Canada Gazette, Part I) requirements for two types of Health Canada regulatory submissions: amendments to Schedule F (governs prescription drug status) and Table II in Division 15, Part B (establishes Maximum Residue Limits for pesticides in foods).  Preserves rigorous scientific review and maintains existing consultation with stakeholders and trading partners.	Health Canada (lead), International Trade Canada (ITCan), Privy Council Office (PCO).	On target with March 2005 commitments.  A 30-month pilot began on February 23, 2005 and will continue through September 2007. The modified processes will be evaluated using indicators, such as the total time required to complete a regulatory amendment, and the number of stakeholder comments. If the modifications are found to be successful in reducing the time needed to process regulatory amendments, Health Canada may seek the support of PCO and Treasury Board for using the modified processes on an ongoing basis.  Health Canada has identified the first seven regulatory amendments that will follow the modified process. Target for publication in <i>Canada Gazette</i> , Part II is winter 2005–2006.

Initiative	Lead and Participants	Progress Update and Next Steps
Multi-stakeholder Task Force on Trans Fat:  Recommendations and strategies to reduce trans fats in Canadian foods to the lowest levels possible includes representatives of the food processing and food service industries, health associations, government, and academia.	<ul> <li>Health Canada and the Heart and Stroke Foundation of Canada co-chair the task force.</li> <li>Representation from the following participants:</li> <li>Federal-Provincial/Territorial (FPT) Group on Nutrition (provincial representative)</li> <li>FPT Food Safety Policy Committee (provincial representative)</li> <li>Agriculture and Agri-Food Canada (AAFC)</li> <li>Canadian Food Inspection Agency (CFIA)</li> <li>Agri-food industry sector along full continuum from production to retail and food service</li> <li>Disease/health voluntary non-governmental organization (NGO) sectors</li> <li>Academia</li> </ul>	On target with March 2005 commitments.  The task force held public consultation in June 2005.  Interim report was released in August 2005. Includes recommendations regarding public education, labelling and immediate opportunities to reduce trans fat content in Canadian foods.  A second public consultation followed by a task force meeting is planned for October/November 2005.  Task force recommendations and a final report to the Minister of Health on an appropriate regulatory framework are expected by the end of 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Standards-based Regulatory Framework for Cells, Tissues, and Organs (CTOs):  A new regulatory framework based on standards published by the Canadian Standards Association (CSA) in June 2003. The goal is to balance the need for safe, high-quality CTOs with the need to ensure availability for transplantation.  The regulatory framework will be implemented in two phases: Phase I will focus on safety regulations, while Phase II will focus on adverse event reporting and establishment compliance.  The 2003 standards have been updated to reflect changes in technology and disease prevention developments. The second edition of the standards will be released in 2006.	Health Canada (lead), Public Health Agency of Canada, CSA.	On target with March 2005 commitments.  Cross-Canada stakeholder consultation on Phase II completed in March 2005.  Revised interim guidance document prepared and released in August 2005.  Educational CDs available September 2005.  Comprehensive cost-benefit analysis for Phase II of the regulations completed in September 2005.  Consultation with provinces/territories took place in October 2005.  Target for publication of draft regulations in Canada Gazette, Part I, fall 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Improving Drug Review Performance (supported by Therapeutics Access Strategy):  Funding was provided through budget 2003 to put in place initiatives that would allow Health Canada to reach internationally comparable drug review time targets by 2006 for pharmaceuticals. Review times are being improved through efficiency gains (such as the introduction of project management tools and approaches) and increased Health Canada review capacity, without compromising safety.	Health Canada (lead)	On target with March 2005 commitments.  The review backlog of pharmaceutical submissions has been eliminated and review times have substantially improved. Between January and September 2005, 58 percent of completed reviews of pharmaceutical submissions were within time targets (compared to 25% in 2004 and 13% in 2003).  For pharmaceutical submissions, Health Canada expects to reach the international threshold (90% of submissions reviewed within time targets) by March 2006.  As part of its ongoing review, Health Canada is developing a plan to sustain gains that have been made and further improve the drug review process.

Initiative	Lead and Participants	Progress Update and Next Steps
Electronic Pest Management Regulatory System (e-PRS):  Launch of the world's first web-based service for conducting pesticide regulatory activities, including	PMRA (lead), industry, FPT and international working groups.	The proposed pilot of the on-line system did not go ahead as planned in Spring 2005, in order to allow for the integration of other modules that will facilitate the electronic and on-line submission of additional
submission of product information and adverse event reports.		information that will be required under the new Pest Control Products Act.
System uses secure government channels to allow industry to send information directly to the Pest Management Regulatory Agency (PMRA) and for PMRA to work with the information online.		While an application can now be downloaded to assist industry in compiling electronic regulatory submissions and submitting them on CD, the on-line system is not yet available.
to Nork was the meaning of chime.		An electronic index builder, which will help industry and the PMRA to create and process submissions was released in September 2005.
		The launch of the on-line regulatory system will occur in 2006 in concert with the new <i>Pest Control Products Act</i> and regulations.

Initiative	Lead and Participants	Progress Update and Next Steps
Consolidating Federal Environmental Assessments:  Based on a commitment in the October 2004 Speech from the Throne to consolidate federal environmental assessments. Through consolidation, the Canadian Environmental Assessment Agency (CEAA) will take on a greater role in the environmental assessment of projects. More timely environmental assessments and greater certainty will result from reduced process delays and improved coordination among some 30 federal	CEAA (lead). Departments, agencies and bodies designated as "federal authorities" under the <i>Canadian Environmental Assessment Act</i> , such as Natural Resources Canada (NRCan), Fisheries and Oceans (DFO) Canada and Environment Canada.	Consultations, including special meetings of the multi- stakeholder Regulatory Advisory Committee, were held in August and September 2005 on options for a new model in which the CEAA will take a greater role in assessment of projects. At the request of industry associations, environmental groups and others, consultations will continue in order to define, by spring 2006, effective and viable models for environmental assessment consolidation.
improved coordination among some 30 federal organizations.		Other improvements will be implemented concurrent with development of the new model. Bilateral agreements with provinces or territories are being reviewed and improved where necessary. These agreements will ensure coordination where multiple jurisdictions are involved in the environmental assessment of a project. Seven agreements are in place; since the last report, two have been renewed. A third will be renewed by winter 2006.
		Two new agreements under development are expected to be finalized this winter.
		Proposed regulatory changes to reduce assessments of small projects will be brought forward by the end of December 2005.
		Other changes to strengthen federal coordination will be brought forward by the end of March 2006.

Initiative	Lead and Participants	Progress Update and Next Steps
Environmental Process Modernization Plan (EPMP):  A five-part plan to make DFO's fish habitat management program more effective, results-based, transparent, effective, predictable and efficient. Elements are as follows:  Delivery of the Habitat Management Program based on a risk management framework;  Streamlined regulatory reviews;  Strengthened partnerships;  A new management model for environmental assessments for major projects; and  Increased predictability and timeliness in decision making.  A sixth component of the EPMP is Habitat Compliance Modernization (see Section 6, "New Departmental Initiatives").	DFO (lead). Federal agencies with a mandate on resource management and the environment, including NRCan, Agriculture and Agri-Food Canada (AAFC), Environment Canada, NEB, Transport Canada and CEAA.  Provincial and territorial: departments (i.e., resource management, environment, transportation) through the Canadian Council of Fisheries and Aquaculture Ministers (CCFAM) and its task groups.  Federation of Canadian Municipalities (FCM)  Resource industry stakeholders through the National Resource Industry Association (NRIA).  NGOs through the Coalition of National/Regional Non-Governmental Conservation Organizations.  Aboriginal organizations, including the Assembly of First Nations and a wide range of provincial and local level Aboriginal groups and communities, particularly in the inland provinces.	On target with March 2005 commitments.  Spring 2005: Completed qualitative risk management framework. Explains how sensitivity of fish and fish habitat and the severity of impact of a specific activity around or in water, determines the level of risk associated with different development activities.  Spring 2005: Completed 13 national operating statements that provide clarity to proponents on habitat protection requirements for the majority of low-risk development activities.  Spring 2005: Started consultations with all provinces and territories on applying the risk management framework and the operating statements to their regulatory processes and promoting single-window service delivery.  Spring 2005: Broad-based senior-level policy meeting led to bilateral discussions of adopting single-window service delivery in individual provincial jurisdictions.  Summer 2005: New organizational model implemented to strengthen effectiveness and timeliness of environmental assessments for major projects across DFO.  Fall 2005: Internal governance and policy initiatives implemented to improve predictability and timeliness in decision making, including the launch of mandatory training for all program staff.  Discussions ongoing on partnering opportunities with provinces/territories that have not yet entered into bilateral agreements on fish habitat.  DFO will continue to implement elements of the EPMP, with emphasis on internal communications to ensure that DFO staff are familiar with the Department's plans and to ensure consistency in program delivery.

Initiative	Lead and Participants	Progress Update and Next Steps
Competitiveness and Environmental Sustainability Framework (CESF):  Lays out a broad vision of attaining the highest level of environmental quality as a means of enhancing the health and well-being of Canadians, preserving our natural environment, and advancing our long-term competitiveness.  Aims to integrate economic and environmental signals through improved environmental management in five key areas: science and technology, information, performance promotion and enforcement, education and engagement, and decision making.  Key to implementation are Sector Sustainability Tables (see Section 6, "New Departmental Initiatives").	Environment Canada (lead), OGDs, provinces/territories, industry, Aboriginal groups, NGOs.	On target with March 2005 commitments.  Federal-Provincial/Territorial (FPT) Framework Agreements: Ministers accepted a draft <i>Commitment Statement on Environmental Sustainability in Canada</i> in June 2005.  The statement sets out a common vision for achieving the highest level of environmental quality as a means to enhance the well-being of Canadians, preserve the environment, and advance the competitiveness of Canada's economy. Final approval expected at fall 2005 Canadian Council of Ministers of the Environment (CCME) meeting.  Bilateral discussions are underway with Atlantic, Saskatchewan, British Columbia and Alberta to identify areas for collaboration, outcomes and initiatives in order to put the principles into action.  2006: Bilateral implementation agreements on areas identified for collaboration will be developed with interested provinces.

Initiative	Lead and Participants	Progress Update and Next Steps
Pulp and Paper Air Quality Forum:	Forum, chaired by industry CEO, includes:	On target with March 2005 commitments.
Exploring innovative approaches to managing air emissions, such as linked federal and provincial requirements and instruments; fiscal incentives for major environmental performance improvements; and breakthrough technologies.	Environment Canada (lead),	Technical advisory group reported to the forum when it met in September 2005 and agreed to develop a 10-year action plan to reduce air emissions.  Third forum meeting scheduled for February 2006.  Approval of 10-year action plan to reduce air emissions expected in spring 2006.
	Health Canada, NRCan (observer),	
	<ul> <li>Provinces of British Columbia, Ontario, Quebec, Alberta and Newfoundland and Labrador,</li> </ul>	
The forum established a technical advisory committee charged with listing priority emissions and related FPT regulatory initiatives and incentives.	Aboriginal groups, and	
	Environmental NGOs.	. Process of 2 and

Initiative	Lead and Participants	Progress Update and Next Steps
Memorandum of Understanding (MOU) on Telematics:  Agreement with automotive manufacturers on safety of invehicle telematics devices (e.g., navigation and entertainment systems, Internet access, cell phones).  Will include a process-oriented safety standard and the general principles and process elements that should underpin product design, development, evaluation, manufacture and installation.	Transport Canada with automotive industry associations and automobile manufacturers.	Progress is slower than envisioned.  A joint industry-government group has been working to establish the terms of the MOU and the content of the process-oriented standard (i.e., safety management system).  A draft MOU has been prepared and dialogue is ongoing with industry to clarify the nature and scope of the MOU.  A sample involving four currently available telematics devices was evaluated this year. Future devices will be evaluated and compared to this benchmark in order to assess the impact the MOU will have on safety. Manufacturers will also monitor the impact of the MOU on their products.  A report describing telematics consultation and resulting initiatives was posted on the Transport Canada website in September 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Safety Management System Regulations	Transport Canada with aviation stakeholders.	On target with March 2005 commitments.
for Aviation Organizations:  A formalized framework that integrates safety		The first series of regulations that apply to air operators came into effect on May 31, 2005.
considerations into every level of decision making in aviation organizations.  Will foster stronger safety cultures within the civil aviation industry and, as a consequence, improve safety practices.		The second stage is to apply the concept of safety management systems to other areas of the aviation industry. Consultations with industry took place in June and September 2005 to review proposals for the standardization of the regulations through the <i>Canadian Aviation Regulations</i> (this will apply to airports, air navigation services and flight training units).  Publication in <i>Canada Gazette</i> , Part 1 is scheduled for early 2006.

Initiative	Lead and Participants	Progress Update and Next Steps
Canadian Biotechnology Strategy:  A key challenge in regulating novel and emerging products of biotechnology is the fast pace of scientific change that crosses conventional lines of regulatory authority.  The renewed Canadian Biotechnology Strategy is an interdepartmental initiative that will include a policy framework and action plan aimed at improving the regulation of such products and enhancing the capacity of regulators to respond more quickly to innovation.	Industry Canada (lead) and the following departments with specific regulatory responsibilities for products of biotechnology:  Canadian Food Inspection Agency (CFIA),  Environment Canada,  Fisheries and Oceans Canada (DFO), and  Health Canada.	Progress in this complex area needs to be accelerated.  Fall 2005: Industry Canada, in conjunction with other departments, will develop an overall policy framework on how the Government will address novel biotechnology products in Canada.  Once a policy framework has been developed, an action plan, including mechanisms to strengthen interdepartmental co-operation and better define regulatory responsibilities, will be developed. During policy development, further definition and clarification of regulatory challenges will occur in certain areas, such as animal biotechnology and molecular farming.  Of the areas under review, progress has been made in aquatic biotechnology.  Early 2006: DFO will share a regulatory plan for aquatic-specific biotechnology, which will provide a streamlined approach for industry stakeholders on regulatory matters related to aquatic organisms.

Initiative	Lead and Participants	Progress Update and Next Steps
New Government of Canada Bioportal (biotech.gc.ca):  Internet one-window access to clear and comprehensive information on biotechnology and its applications.  Components include bioregulations.gc.ca, a tool for navigating the biotechnology regulatory system; and biobasics.gc.ca, which provides general biotechnology information.	Canadian Biotechnology Secretariat (CBSec) with partner departments and agencies including: Health Canada, Environment Canada, CFIA, DFO, Industry Canada, AAFC, International Trade Canada/Foreign Affairs Canada, and Justice Canada.	On target with March 2005 commitments.  Site launched December 1, 2004.  Summer 2005: Addition of easy-to-access links and overviews of regulatory process phases.  The BioPortal was given a five-star rating by Biotechnology Focus magazine in June 2005 issue.  Winter 2006: CBSec will work on enhancement of the BioRegulations component of the site.

Initiative	Lead and Participants	Progress Update and Next Steps
Charities Regulatory Reform:	Canada Revenue Agency (lead)	On target with March 2005 commitments.
Responds to the 75 recommendations of the Joint Regulatory Table (established under the Voluntary Sector Initiative) on improving the legislative and regulatory environment within which the charitable sector operates.	A sector advisory group, the Charities Advisory Committee, was created for consultation, advice, and guidance.	Legislative amendments received royal assent on May 13, 2005. New ministerial authorities to support an appeal process, and improved sanction regime came into effect on June 12, 2005.
Initiative includes <i>Income Tax Act</i> amendments, policy and program elements, information systems development,		Several public awareness and sector outreach initiatives were completed May–July 2005.
staff training, and organizational/operational changes. Will allow for a quicker resolution of disputes and greater transparency of charity practices and decisions about how they are regulated.	ater	Ongoing: Consultation with Charities Advisory Committee concerning approaches to intermediate sanctions, specifically, suspending qualified donor status, and options for dealing with deceptive fundraising.
		Implementation of intermediate sanctions program scheduled for fall 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Aquaculture Framework Agreement (AFA):	DFO (lead)	On target with March 2005 commitments.
<ul> <li>Aquaculture is an area of shared Federal-Provincial/Territorial (FPT) jurisdiction in Canada. Renewing aquaculture governance through development of this framework will result in the following achievements:</li> <li>Clearly define roles and responsibilities between different levels of government;</li> <li>Eliminate duplication and promote cost-sharing;</li> <li>Strengthen FPT collaboration;</li> <li>Standardize environmental monitoring process and activities to streamline application processes while maintaining strong environmental protection;</li> <li>Support consistent, credible decision-making processes that consider environmental and socio-economic factors; and</li> </ul>	DFO (lead)  Main partners: CFIA, Environment Canada.  Other partners and stakeholders: Department of Foreign Affairs and International Trade Canada (DFAIT), AAFC, provinces and territories, First Nations, Canadian Council of Fisheries and Aquaculture Ministers (CCFAM), and industry (e.g., aquaculture, fisheries, fish processing).	On target with March 2005 commitments.  Progress report to FPT ministers and signing of agreement in principle: October 6, 2005.  DFO is currently completing meetings. Formal consultations with First Nations, industry and other stakeholders are expected to begin in winter 2005–2006.  Commence FPT negotiations: target, January 2006.  Ratification of draft framework by all jurisdictions: target, spring 2007.  Ratification of implementation agreements with individual jurisdictions: target, 2008.
that consider environmental and socio-economic factors; and		

Initiative	Lead and Participants	Progress Update and Next Steps
BizPal:	Industry Canada (lead)	On target with March 2005 commitments.
A web-based service that will allow businesses to easily generate a customized list of the permits and licences required by all levels of government. Will be delivered	Ontario, British Columbia, Yukon, and three municipalities: Whitehorse, Kamloops and Halton Region (including Halton Hills and Milton) are involved in the pilot.	The process of getting permits and licences for 233 types of businesses has been mapped in participating jurisdictions.
through websites, call centres, and in-person service outlets of participating governments. Currently a pilot project in a limited number of jurisdictions.	The Province of Manitoba and the City of Ottawa have officially confirmed their participation in an expanded project.	Entrepreneurs within the partner jurisdictions will be able to access BizPaL and its online permit and licence wizard in October 2005.
		Planning for expansion activities has begun. Timeline for expansion will be developed based on success of pilot.

Initiative	Lead and Participants	Progress Update and Next Steps
Guiding Principles and Recommended Practices affecting domestic and multi-jurisdictional merger reviews:  Under development by the Competition Bureau, through the International Competition Network (ICN). The development of internationally accepted merger review guidelines will assist in providing firms with greater certainty and predictability concerning issues such as the time for completing a merger review.	The Competition Bureau and over 90 other national or multinational competition agencies belong to the ICN.  Co-operation from international organizations (e.g., Organisation for Economic Co-operation and Development, World Trade Organization, United Nations Conference on Trade and Development), associations and practitioners of anti-trust laws and economics, industry and consumer associations, and members of the academic community.	On target with March 2005 commitments.  The Mergers Notification and Procedures Subgroup recently completed work on two new recommended practices and three reports, which were approved at the ICN annual conference in Bonn, Germany in June 2005.  A number of jurisdictions have already used the recommended practices to improve their merger review procedures. (Canada already complies with the vast majority of the recommended practices.)  ICN members adopt work products at their annual conferences. The next ICN annual conference will be held in Cape Town, South Africa in May 2006.

Initiative	Lead and Participants	Progress Update and Next Steps
Not-for-Profit Corporations Act:  Will provide improved financial accountability and transparency, clarify the role of directors, and protect the rights of members of not-for-profit corporations.	Industry Canada (lead)  Department of Justice, Revenue Canada, Department of Finance, Public Security and Emergency Preparedness Canada, Heritage Canada.  A wide variety of stakeholders, including not-for-profit organizations, bar associations, and the accountancy profession.	The legislation received first reading on November 15, 2004 and is now before the Standing Committee on Industry, Natural Resources, Science and Technology for review.  The committee has held three hearings with witnesses representing Industry Canada and stakeholders from the voluntary sector and the accounting profession. The committee is expected to continue its examination of the bill in fall 2005.  Once the bill is approved, a regulatory package will be developed to guide implementation.

Initiative	Lead and Participants	Progress Update and Next Steps
Paperwork Burden Reduction Initiative:	Industry Canada (lead)	On target with March 2005 commitments.
Involves measuring the costs and impact of regulatory compliance on small businesses and pursuing opportunities to simplify regulatory requirements across federal departments and agencies.  The initiative consists of three key components:  • A public/private sector Advisory Committee on Paperwork Burden Reduction;  • A Statistics Canada Survey of Regulatory Compliance Costs; and  • Annual progress reports to the Minister of Industry.	Committee includes the following representatives:  Small businesses and business associations, including  Canadian Federation of Independent Business  Canadian Manufacturers and Exporters  Canadian Payroll Association  Greystone Energy Systems Inc.  Gryzko Harper Chartered Accountants  PBB Global Logistics  Simpson Seeds Inc.  Provincial/federal departments  British Columbia Ministry of Management Services  Ministère du Conseil exécutif, Gouvernement du Québec  Canada Revenue Agency  Finance Canada  Human Resources and Skills Development Canada	The key components of the initiative are on schedule and within budget.  The advisory committee has held three meetings since its creation in March 2005.  The committee endorsed Statistics Canada's Survey of Regulatory Compliance Costs in March 2005 and recommended development of an inventory of administrative requirements.  A suggested approach and work plan for the Inventory of Administrative Requirements was reviewed by the committee in September 2005.  Data collection for the Survey of Regulatory Compliance Costs will begin in October 2005. Initial results will be published July 2006. Full survey results will be released in December 2006.  The committee will present its first annual progress report to the Minister of Industry in December 2005.
	Treasury Board of Canada Secretariat	

Initiative	Lead and Participants	Progress Update and Next Steps
Modernizing the Telecommunications Framework.	Industry Canada (lead), CRTC, Competition Bureau,	It is expected that legislation will be tabled in fall 2005.
1. Amendments to the <i>Telecommunications Act</i> —Administrative Monetary Penalties Regime:	Justice Canada.	
Providing the Canadian Radio-Television and Telecommunications Commission (CRTC) with powers to impose administrative monetary penalties for its decisions and for violations of the <i>Telecommunications Act</i> . Will allow for greater regulatory flexibility, more appropriate penalties, and more timely, flexible and effective responses for violations of CRTC decisions or the Act.		

Initiative	Lead and Participants	Progress Update and Next Steps
Modernizing the Telecommunications Framework.  2. Spam Task Force Report:  Further to consultations begun in 2002 with industry and consumer organizations, the Anti-Spam Action Plan for Canada was developed. On May 11, 2004, a joint government-private sector task force was convened to oversee the implementation of the plan to control the spread of spam and spyware.	Industry Canada (lead), Competition Bureau, the Office of the Privacy Commissioner, Justice Canada.  Task force included representatives from Internet service providers (ISPs), e-marketers, government and consumers.	On target with March 2005 commitments.  The task force work led to a self-regulation approach for industry through the development of best practices for ISPs and other network operators, and guidelines for commercial e-mail marketing. It also launched a communications campaign to inform users of measures to limit the volume of spam.  On May 17, 2005, the task force delivered its final report, <i>Stopping Spam: Creating a Stronger and Safer Internet</i> , highlighting that a multi-faceted and multi-stakeholder approach is necessary.  A key recommendation is a call for new legislation to deal with spam and related threats to the safety and security of the Internet.  Legislation is expected to be tabled by late 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Modernizing the Telecommunications Framework.	Industry Canada (lead)	On target with March 2005 commitments.
3. Amendments to the <i>Telecommunications Act</i> —Telecommunications Policy Review:		On April 11, 2005, the Industry Minister established the Telecommunications Policy Review Panel.
To ensure that the telecommunications industry continues to support Canada's long-term competitiveness, the		The review panel held consultations with stakeholders between June and October 2005.
Government appointed a panel of eminent Canadians to review Canada's telecommunications framework. The panel will be asked to make recommendations on how to move Canada toward a modern telecommunications framework in a manner that benefits Canadian industry and consumers.		The panel is expected to report its recommendations to the Minister by December 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Modernizing the Telecommunications Framework.  4. Amendments to the <i>Telecommunications Act</i> —Wireless Number Portability:  Allows subscribers to adopt a new wireless service provider while retaining the same telephone number used with a previous service provider. Offers convenience to subscribers seeking to change providers without having to notify business/personal contacts, and update directory listings and stationary.  Responds to demand for wireless number portability by the public, consumer groups, and some wireless service providers.	CRTC (regulatory issues) and Industry Canada (policy issues) (leads)  Stakeholders include the Canadian Wireless Telecommunications Association (CWTA), representing Aliant Mobility, Bell Mobility, Bruce Municipal Telephone System, MTS Mobility, Rogers Wireless (including Fido), SaskTel Mobility, Sogetel Mobilité, Télébec Mobilité, TBayTel Mobility and TELUS Mobility.	On target with March 2005 commitments.  Industry Minister wrote to the Chair, CRTC, encouraging expeditious movement to implement wireless number portability in March 2005.  CWTA announced in April 2005 that Canada's wireless carriers have voluntarily agreed to implement initiatives in Canada. The CWTA convened a task force, with Industry Canada and CRTC as observers. Task force released its plan in September 2005 with implementation proposed for mid 2007.  Implementation of the plan will require regulatory changes. The CRTC sought public comment on this issue in September and October 2005.

Initiative	Lead and Participants	Progress Update and Next Steps
Amendments to the Competition Act:	Competition Bureau	Legislation was introduced in the House of Commons in November 2004.
Proposed amendments will provide authority for the Commissioner of Competition to carry out the following:		The bill is before the Standing Committee on Industry,
Seek restitution for consumer loss resulting from false or misleading representations;		Natural Resources, Science and Technology; review is expected to occur in winter 2005–2006 session.
<ul> <li>Introduce a general administrative monetary penalty provision for abuse of dominance in any industry;</li> </ul>		
Remove the airline-specific provisions from the Act to return it to a law of general application;		
<ul> <li>Increase the level of administrative monetary penalties for deceptive marketing practices; and</li> </ul>		
Decriminalize the pricing provisions.		
These amendments will result in a strengthened competition framework. Remedies under the Act will promote timely and voluntary compliance, and will be consistent with competition laws in other jurisdictions, including trading partners.		

Theme: Aboriginal Prosperity and Northern Development

Initiative	Lead and Participants	Progress Update and Next Steps
Bill C-54, the proposed <i>First Nations Oil and Gas and Moneys Management Act</i> :  Will allow First Nations to assume direct control over oil and gas resources on on-reserve lands (and related revenues), and assume control over moneys held for them in the Consolidated Revenue Fund under the <i>Indian Act</i> .  Helps to fulfill the Government's commitment to improve access to resources and timely economic development opportunities for First Nations.	Jointly developed over the past decade by Indian and Northern Affairs Canada (INAC) and First Nations with significant oil and gas reserves on their lands. Three First Nations currently involved: White Bear First Nation (Saskatchewan); Blood Tribe (Alberta); and Siksika First Nation (Alberta).	On target with March 2005 commitments.  Introduced in House of Commons June 1, 2005. Completed second reading, October 6, 2005. Awaiting committee approval.  Subject to passage of the legislation, there is a requirement to complete a First Nation Transfer Agreement between INAC and the three sponsoring First Nations. Also required is an agreement with the provinces providing for the administration and enforcement of oil and gas laws as they relate to environmental protection and resource conservation.  To opt into this legislation, First Nations must ratify a transfer agreement through a community vote.

Theme: Aboriginal Prosperity and Northern Development

Initiative	Lead and Participants	Progress Update and Next Steps
First Nations Fiscal and Statistical Management Act:  Enables First Nations to build fiscal and statistical capacity through the creation of organizations such as a Financial Management Board and a Statistical Institute to support effective government. It provides for practical tools in the areas of property taxation, bond financing, and financial and statistical management in support of social and economic development.  Once the Act comes into force, participating First Nations will have the same access to capital markets available to other governments, a strengthened real property tax system with better representation for taxpayers, and the tools to develop appropriate financial standards and increased capacity in the areas of financial management and use of statistical information.	First Nations-led, in conjunction with INAC.	The Act received royal assent in March 2005 and is expected to come into force in April 2006.  Consultations on nine proposed regulations required to implement FSMA were completed in September 2005. Regulations are being drafted.  Publication of draft regulations in <i>Canada Gazette</i> , Part I: target, winter 2006.

Theme: Aboriginal Prosperity and Northern Development

Initiative	Lead and Participants	Progress Update and Next Steps
Co-operation Plan for the Environmental Impact Assessment and Regulatory Review of a Northern Gas Pipeline Project:  Designed to create a streamlined and simpler review process for the Mackenzie Gas Project. Brings together 14 environmental assessment and regulatory authorities in the Northwest Territoies (NWT) to minimize duplication and delay in environmental assessment, and permit issuances needed to build a pipeline. Plan is a key element in the construction of a pipeline that will bring significant short- and long-term economic benefits while protecting the environment.	Leads: National Energy Board (NEB), Canadian Environmental Assessment Agency (CEAA), Mackenzie Valley Environmental Impact Review Board (MVEIRB).  Other participants: INAC, Mackenzie Valley Land and Water Board (MVLWB), Gwich'in LWB, Sahtu LWB, NWT Water Board, Environmental Impact Review Board for the Inuvialuit Settlement Region, Joint Secretariat for the Inuvialuit Settlement Region, Environmental Impact Screening Committee for the Inuvialuit Settlement Region, Inuvialuit Game Council, Inuvialuit Land Administration, and Inuvialuit Land Administration Council.	Ongoing commitment to collective work.  Collective work continues on further defining where co-operation is needed in the regulatory review process. This work involves detailed mapping of the regulatory process by regulators.  Imperial Oil and its partners have been working with stakeholders to resolve issues in advance of public hearings taking place. Project proponents have committed to advising the NEB and Joint Review Panel (JRP) in November 2005 about whether they are willing to proceed with public hearings.  Public hearings of the JRP regarding environmental assessments will be held concurrently with the NEB review to determine the public need for the pipeline. Both processes are ready to proceed.



6. New Departmental Initiatives

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
New Tools to Improve Safety and Transparency of Regulatory System for Therapeutic Products:  Measures to strengthen the safety of therapeutic products and enhance transparency in Health Canada regulatory decisions. Includes establishment of two regional adverse drug reaction centres, recent public hearings on COX-2 inhibitors and silicone gel-filled breast implants.	Involvement of stakeholders throughout the drug review process.  Better protection of health and safety of Canadians.  More open and transparent process by involving the public and patients in drug safety issues.  Patient participation in determination of acceptable risk for promising therapies.	Patients and health professionals: Better information on safety and effectiveness of therapeutic products, resulting in increased public confidence.  Industry and other stakeholders: Regulations that better address emerging issues and risks, and improve regulatory performance.  Patients, stakeholders and health professionals: Ability to participate effectively in health product regulatory processes.	Health Canada (lead) Provinces and territories (through the National Pharmaceuticals Strategy). Stakeholder organizations (patient and consumer groups, industry, etc.).	Two regional adverse drug reaction centres established in Manitoba and Alberta: April 2005.  Public forum on selective COX-2 inhibitors: June 2005.  National consultations held to examine approaches for increasing public access to clinical trial information: summer 2005.  New website, MedEffect Canada (see www.hc-sc.gc.ca) launched to increase access to health product safety information and enable timely filing of adverse reaction reports: August 2005.  Expert Advisory Panel and public forum on silicone gel-filled breast implants: September 2005.  Short-term objectives:  Establish Health Products Safety Board in the summer or fall 2006 to serve as forum for public input on safety issues and to support risk-benefit assessments of therapeutic products. Public consultations expected in early 2006.  Develop national approach to clinical trial registration and evaluate current clinical trial regulatory framework in 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Product Licensing Framework:  A participatory and risk-based drug licensing model that will support early access to promising new drug therapies while continuously monitoring and reassessing for potential safety, quality, efficacy and effectiveness concerns throughout the product's life cycle. The framework will  • provide a tiered model of authorization for drug products based on risk of the product;  • allow Health Canada to attach conditions to authorization of drug products (graduated licensing);  • allow ongoing collection and dissemination of data; and  • provide greater generation of, access to, and exchange of trusted and reliable information.	Developed with participation from government and the public (industry, patient groups, academia, etc.).  Involves stakeholders throughout the drug review process.  Enables patient participation in determination of acceptable risk for promising therapies.  Enhances risk management and collection of safety data.  Facilitates international co-operation and makes use of international information and reviews.  Contributes to greater transparency.  Promotes efficiency of the regulatory process and fosters innovation in areas of public health.  Establishes an innovative and comprehensive model based on product life cycle.  Increases leadership profile owing to the achievement of efficiency in the drug review process by focusing resources on highest risk drugs.  Enhances public confidence in the drug review system.	Patients and health professionals: Enhanced access to new therapies due to tiered authorization model based on risk. Access to ongoing, updated safety and effectiveness information throughout the life cycle of the drug, thus enhancing treatment option decisions.  Provinces and territories: Ability to make more informed decisions on drug coverage issues due to availability of effectiveness data via closer interaction with Health Canada during drug development and monitoring. Ability to promote drug development and review in areas of public health need.	Health Canada (lead) Industry Canada, Public Health Agency of Canada (PHAC), Patented Medicines Prices Review Board, International Trade Canada.  Provinces and territories via Canadian Coordinating Office for Health Technology Assessment (CCOHTA), Canadian Institute for Health Information (CIHI), health professionals, patient advocacy groups, Canadians.	Draft Product Licensing Framework to be developed by March 31, 2006, including a stakeholder participation plan.  Amendments to the <i>Food and Drug Regulations</i> will be linked to regulatory review under ongoing Health Protection Legislation Renewal.  The first phase of amendments (to cover highest and lowest risk products) to be completed by December 2007.  The second phase of amendments (to cover medium-risk products) to be completed by December 2008.  This initiative will also involve amendments to the <i>Food and Drug Regulations</i> as a whole to implement the Product Licensing Framework.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Use of International Reviews within the Review Process for Biologics:  Aim is to reduce the current backlog of submissions and enhance the efficiency of the review process.  Health Canada currently has 50 biologic drug submissions in backlog, and has committed to eliminate that backlog by March 31, 2007. While information from other jurisdictions is used in the current review process, its use is not consistent or systematic. Evaluation of results of this project will include looking at the impact of using international information on performance and time required to complete reviews.	Ensures cost efficiency and timeliness by avoiding overlap and duplication in review process.  Protects the public interest by providing sufficient regulatory oversight.  Makes use of the best knowledge in Canada and worldwide by using international regulatory expertise more consistently without compromising the quality of the review process.  Promotes effective cooperation, partnerships and processes by involving stakeholders in development of policy.  Promotes risk management approach by identifying ways in which foreign review can be used.  Reduces compliance burden and implements a more efficient regulatory process.	Health care practitioners: Timelier access to drugs for patient care.  Patients: Faster and increased access to drugs.  Industry: Shortened review times and increased international co-operation.  Health Canada: Increased ability to meet established performance targets by applying lessons learned.	Health Canada (lead), Foreign Affairs Canada.  Industry associations (BIOTECanada, Rx&D), patient advocacy groups.	Stakeholder consultations held September 2005.  Policy development underway.  Five priority biologics submissions are currently in backlog. Target to eliminate these submissions from backlog, December 2005.  Eliminate overall backlog in biologics: target, March 2007.  Information from the initial pilot will be used to develop longer term mechanisms to integrate the use of foreign review information into drug review.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Office of Paediatric Initiatives (OPI):  Creation of a new office to be the focal point within the Health Products and Food Branch of Health Canada for an integrated approach to a range of health and safety issues affecting children. A key issue is the availability of comprehensive information on the effectiveness and safety of health products for children and the safety and nutrition of their food.	Provides incentives to stimulate and guide appropriate paediatric studies and generate information.  Provides opportunities to collaborate regulatory initiatives with those of other jurisdictions.  Involves stakeholders through an external expert advisory committee to be created to guide these activities.	Health professionals: Better evidence and more accessible information.  Consumers (particularly parents and caregivers): Improved and more accessible information on therapeutic and diagnostic products and foods used or consumed by children.  Children and youth: Improved health and nutrition.	Health Canada (lead), PHAC.  Stakeholders include health care professionals and their associations, academic researchers, industry, and the Canadian public.	OPI governance and committee structures have been established.  Consultations are being held with stakeholders on proposed amendment to the <i>Food and Drug Regulations</i> that would offer additional market exclusivity as an incentive to generate paediatric data from clinical trials of new drugs: fall 2005.  Finalize work on terms of reference and nomination and selection process for Expert Advisory Committee. Commence work on policy framework: fall or winter 2005.  Convene first meeting of Expert Advisory Committee: spring 2006.

New Regulatory Framework for Radiopharmaceuticals:  Will protect safety of Canadians while contributing to drug access and research international expertise in the nuclear medicine field to determine the components required in a new regulatory framework to address regulatory gaps.  Will protect safety of Canadians while contributing to drug access to safe and effective radiopharmaceutical products for disease treatment and diagnosis.  Patients: Increased access to safe and effective radiopharmaceutical products for disease treatment and diagnosis.  Phased approach:  Release of guidance for use of radiopharmaceuticals in research studies: October 2005.  Report of external consultant on P facility activities: November 2005.					
Radiopharmaceuticals:  Canadians while contributing to drug access and research will make use of domestic and international expertise in the nuclear medicine field to determine the components required in a new regulatory framework to address regulatory gaps.  Canadians while contributing access to safe and effective radiopharmaceutical products for disease treatment and diagnosis.  Institutes for Health Research, Nuclear Medicine Alliance, Canadian Nuclear Safety Commission, Canadian Nuclear Medicine Society, patient advocacy groups.  Release of guidance for use of radiopharmaceuticals in research studies: October 2005.  Report of external consultant on P facility activities: November 2005.	Activity	Why Is It Smart?		Participants	Implementation Status
Radiopharmaceuticals are drugs used for diagnosis and radiation therapy. The current regulations for radiopharmaceuticals under the <i>Food and Drug</i> Regulations are outdated and are not flexible enough to accommodate the need to effectively regulate the safety, and offectiveness of these sell-horsition between sell-horsition between sell-horsition between sell-horsition here.	Radiopharmaceuticals:  Will make use of domestic and international expertise in the nuclear medicine field to determine the components required in a new regulatory framework to address regulatory gaps.  Radiopharmaceuticals are drugs used for diagnosis and radiation therapy. The current regulations for radiopharmaceuticals under the <i>Food and Drug Regulations</i> are outdated and are not flexible enough to accommodate the need to effectively regulate the safety, efficacy and effectiveness of these products while still promoting access and addressing technological advances (e.g., Positron-Emitting Radiopharmaceuticals (PERs), Single Photon-Emitting Radiopharmaceuticals). Existing regulations also do not adequately account for the unique nature of these products (e.g., short half-life, special handling requirements,	Canadians while contributing to drug access and research to enhance health and quality of life.  Will use the best knowledge in Canada and worldwide by facilitating research and clinical development.  Will promote effective cooperation, partnerships and processes by involving stakeholders in development of regulatory framework.  Will promote risk management approach in the design of the new regulations.  Will use a mixture of instruments, including performance-based regulations and supplementary guidance that will result in a more efficient	access to safe and effective radio-pharmaceutical products for disease treatment and diagnosis.  Industry: Clear, modern regulations and appropriate guidance to facilitate compliance.  Hospitals: Clearer regulations for handling and closer collaboration between two regulatory bodies (Health Canada and Canadian Nuclear Safety Commission).  Clinicians and researchers: As users of radiopharmaceuticals in medical research and patient care.  Provincial and territorial governments: Modern regulatory requirements on which to base funding	Institutes for Health Research, Nuclear Medicine Alliance, Canadian Nuclear Safety Commission, Canadian Nuclear Medicine Society, patient	Release of guidance for use of radiopharmaceuticals in research studies: October 2005.  Report of external consultant on PER facility activities: November 2005.  Finalize good manufacturing practices guideline for PERs: December 2005.  Create Expert Advisory Group: January 2006.  Complete regulatory gap analysis: March 2006.  Propose new regulatory framework:

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
New Regulatory Framework for Product-specific Health Claims for Foods:  Will set out the conditions for issuing, on a product-by-product basis, certain types of claims and disease risk reduction claims currently considered drug claims.  The range of health claims currently permitted for foods is limited under the Food and Drugs Act and Food and Drug Regulations. Consequently, food manufacturers are not able to deliver messages about the health benefits of their products using food labels or advertising.	Provides consumer protection from unsubstantiated claims on food products.  Enables more informed choices in purchasing food products.  Includes stakeholders and citizen consultation.	Food producers, manufacturers and importers: Ability to make claims for food products and sell foods with health claims. Improved competitiveness as a result of ability to make claims similar to those permitted in the United States.  Consumers: Ability to choose products that will help maintain and improve health, and in so doing, potentially help reduce incidence of some illnesses and the reliance on health care services.	Health Canada (lead) Agriculture and Agri-Food Canada (AAFC), Canadian Food Inspection Agency (CFIA), Industry Canada, PHAC.  Consultation with food industry associations, health professional associations, consumer groups, provincial and territorial governments.	Consultations: January–February, 2006.  Target date for publication of regulation in Canada Gazette Part I: winter 2007.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
International Health Regulations:  Revised regulations adopted by World Health Assembly in May 2005. Primary aim is to establish a uniform international legal regime for the prevention of, protection against, and control of the international spread of disease. Impose obligations on all levels of government with responsibilities for public health.	Provides opportunity to create a coherent and consistent public health system in Canada by ensuring that public health laws within Canada are uniform and interoperable.  Will involve federal, provincial and territorial, and municipal levels of government in implementation.	Transportation operators, port authorities, provincial and territorial and municipal public health authorities: A common global framework for the movement of travellers, goods and cargo. Adherence to common requirements to prevent the international spread of disease.  Canadians: Overall reduction in the potential spread of communicable diseases.	PHAC (lead), Health Canada.  Provincial public health authorities	Adoption by World Health Assembly: May 2005.  Development of implementation plan (with provinces and territories): target, December 2005.  Implementation plan endorsed by Pan-Canadian Public Health Network: target, March 2006.  Implement plan: 2006–2009.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Expansion of Canada–United States– Mexico Pesticide Joint Review Program to Include Minor-use Products:  New joint minor-use review program involving the Pest Management Regulatory Agency (PMRA) and the US Environmental Protection Agency (US EPA).  Minor-use pesticides are pesticides needed for minor-use crops where the manufacturers do not have sufficient economic interest to provide the necessary data for registration in Canada.	Will increase access to pesticides for minor-use crops for the agricultural industries because they will be available simultaneously in both countries.  Will cut the PMRA's minor-use review workload approximately in half through international work sharing.	Agricultural industry (growers): Simultaneous access to minor-use pesticides submitted for registration in both countries.  Canadian public: Strengthened health and environmental protection and strengthened post-registration controls on pesticides.	PMRA (lead). Agriculture and Agri-food Canada (AAFC), US EPA (as regulatory agency), US Department of Agriculture (USDA) and US IR-4.  Consultations via the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides.	Pilot program underway. Implementation of formal program scheduled to begin January 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Establishment of Board of Directors for the Assisted Human Reproduction Agency of Canada:  A key step toward the establishment of the new Assisted Human Reproduction Agency of Canada under the Assisted Human Reproduction Act.  A national, open and transparent recruitment process has been launched to attract the most qualified individuals from a broad range of backgrounds and disciplines. A screening panel of 10 representatives from the public and private sectors will review applications and make recommendations, following which a committee of senior federal officers will make recommendations to the Minister of Health.	Involves representatives of the private sector assisted human reproduction (AHR) community to ensure the board reflects a range of backgrounds and disciplines relevant to the agency's objectives.  Increases public trust and "buy-in" through transparency and inclusiveness of the recruitment process.  Example of Canadians being actively involved in the constitution of a board that will direct the activities of a federal regulatory agency.	General public and assisted human reproduction professionals: Opportunity to fully participate in the regulatory process. Appropriate regulatory controls and access to new AHR technologies.  General public: Access to safe and ethical AHR technologies.  AHR community: Opportunity to participate in the selection process for the Board of Directors of the Agency that will oversee the AHR sector in Canada.	Health Canada (lead), Privy Council Office.	Recruitment campaign: Launched June 2005.  Screening Panel Review: October 2005.  Appointment of members: early 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Review of Regulations Governing Pre-market Notification for Foods:  A pilot project to review sections of the Food and Drug Regulations that require pre-market safety assessment of foods and authorization of certain products (e.g., food additives, novel foods and infant formulae, etc.) before they can be offered for sale.  The current need for a regulatory amendment to authorize the use of a new food additive adds a significant administrative delay (anywhere from three months to three years) between the completion of the safety assessment and when a company can market a food additive for use in foods or a food containing the food additive.  A regulation is required for each new food additive. Initiative seeks to develop a more efficient and responsive regulatory framework to minimize the delay, after completion of a safety assessment, in permitting the sale of these foods.	Increases responsiveness, predictability and efficiency, while maintaining consumer protection and safety of the food supply.  Involves stakeholder and citizen consultation.  Ensures that regulatory regimes are appropriate.	Industry: More efficient pre-market review processes and more timely market access for their products.  Consumers: More timely access to innovative food products.	Health Canada (lead), CFIA, AAFC, PHAC.  Consultation with food industry sectoral associations, industries developing innovations for the food sector, consumer associations, and provincial and territorial health and agriculture authorities.	Completion of consultation with stakeholders: target, spring 2006.  Proposed regulatory amendments and pre-publication in <i>Canada Gazette</i> Part I target, winter 2007.  Publication of final amendments in <i>Canada Gazette</i> Part II: target, fall 2007.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
An initiative to modernize the compliance and enforcement strategies of Fisheries and Oceans Canada's Habitat Management Program. Aims to promote and enhance compliance with the fish habitat protection provisions of the <i>Fisheries Act</i> .  Part of the Environmental Process Modernization Plan (see updates).	Places emphasis on all elements of the compliance continuum, with increased effort on compliance promotion and monitoring for results.  More focused compliance and enforcement for activities posing greatest risk to fish habitat.  Assists regulated community in developing self-audit programs.  Institutes compliance incentives for public and industry that voluntarily discover, disclose and correct environmental problems. Increased efficiency in delivery of compliance and enforcement activities by following a risk management framework.	Industry: An improved, predictable and equitable level of compliance and enforcement.  Canadians: Better protection for fish habitat for present and future generations.  Fisheries and Oceans Canada: Greater program effectiveness by learning from increased monitoring efforts and incorporating lessons learned into regulatory decisions.	Fisheries and Oceans Canada (lead) Industry stakeholders, non-governmental organizations (NGOs) and environmental stewards.	May 2005: Established national working group to develop National Habitat Compliance Model and Implementation Plan.  Commence anticipatory staffing process in Central and Arctic and Pacific regions: target, January 2006.  Commence implementation, including stakeholder engagement, strategic planning, partnering and monitoring activities: target, April 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Environmental Effects Monitoring:  Brings together experts from outside government to make recommendations to improve the effectiveness and efficiency of pulp and paper environmental effects monitoring (EEM).  Important element of federal <i>Pulp and Paper Effluent Regulations</i> under the <i>Fisheries Act</i> .	Brings together experts from industry, government, and environmental and Aboriginal communities to work with goverment to find innovative ways to improve the efficiency and effectiveness of the program.  Will reduce compliance burden and offer innovative ways of tackling emerging issues.	Industry: Enables more targeted spending of resources on monitoring water quality in problem areas.  Federal government: A more efficient program to administer by allowing Environment Canada to focus resources on higher risk areas.  Environmental groups and public: Improved environmental performance where monitoring has indicated impacts.	Smart Regulation Expert Group: Environment Canada (chair), Fisheries and Oceans Canada and the Privy Council Office.  Also includes two experts from the environmental community, one from the Aboriginal community and four from the pulp and paper industry.	Publication of <i>Improving the</i> effectiveness and efficiency of pulp and paper environmental effects monitoring: A Smart Regulation opportunity. November 2005. Regulatory amendments in place: target, 2007. Major regulatory review to be completed by 2010.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Amendments to New Substances Notification Regulations, developed under sections 89 and 114 of the Canadian Environmental Protection Act (CEPA) 1999:  Provides the framework for the notification and assessment of new substances in Canada.  The primary objective of the new regulations remains the same: To ensure that no new substances are introduced in the Canadian marketplace before an assessment is made of their potential effects on the environment and human health.	More responsive to stakeholder needs.  Significantly reduces assessment periods for certain categories of chemicals.  Developed through consensus.  Reinforces international efforts (Organisation for Economic Co-operation and Development [OECD] Mutual Acceptance of Notification) to increase mutual understanding and acceptance of hazard and risk assessment of new substances, and to identify strategies for overcoming barriers to co-operation by streamlining and simplifying domestic regulatory requirements.	Industry: Changes to administrative and technical requirements will lower costs associated with notification and make compliance less costly.  Canadians: Lower cost and more responsive regulatory system without reducing the level of protection to the environment and human health.	Members of the New Substances Notifications Multi-stakeholder Table include the following federal government participants: Environment Canada, Health Canada, and Industry Canada.  Industry participants: PPG Canada Inc., BASF Canada, Industry Coordinating Group for the CEPA, Dominion Colour Corporation, 3M Canada Inc., Dupont Canada Inc., Procter & Gamble Inc.  Public advocacy groups: Canadian Labour Congress, Great Lakes United, Canadian Environmental Defence Fund, Consumers Association of Canada, Communications, Energy and Paperworkers' Union of Canada, Canadian Environmental Defence Fund, Canadian Public Health Association.  Provinces and territories were provided with an opportunity to comment through the CEPA National Advisory Committee.	The New Substances Notification Regulations (Chemicals and Polymers), the New Substances Notification Regulations (Organisms), and the Regulations Amending the New Substances Fees Regulations were published in Canada Gazette Part II on September 21, 2005. Will come into force on October 31, 2005.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Sector Sustainability Tables:  Four sector-specific tables (forests, mining, energy, chemicals) and one crosscutting issues table have been created to bring together governments, industry, labour, Aboriginal peoples and NGOs to provide informed advice on how to improve environmental performance in ways that support the long-term competitiveness of the sector.  Important implementation tool of the Competitiveness and Environmental Sustainability Framework (see Section 5, "Updates on Departmental Initiatives").	Will inform policy decisions to ensure that better environmental results are achieved in a manner that considers business realities and promotes economic competitiveness.  Continuous improvement and renewal.  Positioned to respond to emerging issues in science, technology and global markets.  Collaborative mechanism to inform policy and actions by bringing together governments, industry, labour, NGOs and Aboriginal representatives.	Canadians: Healthier environment, stronger economy, and engaged society.  Governments: Better use of financial, technical and regulatory resources. Better policy actions through stakeholder input and by taking a comprehensive view on sector and crosscutting issues.  Industry: Enhanced predictability and transparency. Recognition of business realities in policy making. Strengthened long-term competitiveness.	Environment Canada, Natural Resources Canada, Industry Canada, Fisheries and Oceans Canada, Human Resources and Skills Development Canada, Health Canada, Atlantic Canada Opportunities Agency, Transport Canada, and Indian and Northern Affairs Canada.  Forest Products Association of Canada, Mining Association of Canada, Chemical and Allied Industries Group (CAIG), Energy Dialogue Group, and Canadian Environmental Network. Senior representatives of Aboriginal, industry, labour and environmental organizations.	Co-chairs for the first four tables confirmed, spring 2005.  First meetings to be held in fall 2005.  Design meetings (draft terms of reference and membership) for all tables to be completed, November 2005.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Proposed amendments to <i>Nuclear Security Regulations</i> :  A comprehensive and robust set of requirements related to the physical protection of nuclear facilities and nuclear materials in Canada.	Extensive consultation with affected licensees and stakeholders. Incorporates international best practices. Regulations set out minimum requirements common to all nuclear facilities. Facility-specific requirements will be addressed through licence conditions.	Canadian public: Enhanced security of Canada's important nuclear facilities.  Facility operators: Clear statement of expectations and requirements.	Canadian Nuclear Safety Commission (lead), Public Safety and Emergency Preparedness Canada (PSEPC), Natural Resources Canada, Privy Council Office. Licensees	regulations set out in two emergency orders issued post September 11, 2001. Orders resulted in rapid enhancement of security measures and procedures at all affected facilities.  Draft regulations published in Canada Gazette, Part I in October 2003. Consultations led to substantive comments. Regulations amended and published in Part I in June 2005. Target for regulation to come into force: March 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Equivalent Approaches to Aviation Security for North America:  A comprehensive North American strategy for the establishment of equivalent approaches to aviation security. Approach will include developing, testing and implementing comparable standards for the screening of aviation passengers, hold baggage and air cargo.  Will involve working together on passenger assessment programs that reflect each nation's legislation. Will require agreement by Canada, the United States and Mexico.  Part of the Security and Prosperity Partnership (SPP) signed by Canada, the United States and Mexico in March 2005.	Will result in greater consistency and coordination of aviation security and contribute to building public confidence through compatibility between Canada-US-Mexico requirements.  Will address regulatory burden that frustrates a large number of partners involved in North American air transport.	Industry: Streamlined requirements and reduced regulatory divergences.  Air transport sector: Enhanced competition.  Public: Continued high standards of protection	Transport Canada (lead) Supporting departments: PSEPC, Canada Border Services Agency (CBSA), Royal Canadian Mounted Police (RCMP), Canadian Security Intelligence Service (CSIS), and Citizenship and Immigration (CIC). United States and Mexico	<ul> <li>Commitment to develop framework in various stages by June 2008:</li> <li>Develop comparable passenger assessment programs: target, end of 2006;</li> <li>Develop comparable standards and procedures for baggage and passenger screening: target, June 2007; and</li> <li>Develop comparable screening and inspection protocols for goods to improve the security of cargo: target, June 2008.</li> </ul>

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Certification of Aircraft and Related Products, Parts and Appliances, Canadian Aviation Regulation (CAR) 521:  To improve the certification process for aeronautical products and parts by consolidating existing regulations and standards found in several Canadian Aviation Regulations (CARs) into a single regulation and standard (CAR 521).	Will lead to clearly written and more accessible requirements through consolidated regulations.  Aligns Canada's regulatory framework with those of US and European Union (EU) partners.  Streamlines regulatory process through a more efficient, timely and predictable certification program specifying clearly defined roles and responsibilities to all stakeholders involved in the process.	Aviation industry: Regulations that are more closely aligned with US and EU requirements; reduced regulatory burden by creating a single regulatory tool.	Transport Canada (lead)	Consultations took place in 2004–2005 through Canadian Aviation Regulation Advisory Council.  Publication of regulations in <i>Canada Gazette</i> , Part I: target, 2007.

Theme: Safety and Security

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Enhanced Safety Requirements for Dangerous Goods Intermediate Bulk Containers:  A Canadian-led initiative (as part of United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) to enhance safety requirements for manufacturing, testing and filling various types of intermediate bulk containers (IBCs).  IBCs transport large quantities of dangerous goods (up to 3000 litres) such as acids, diesel fuel, gasoline, and other liquids.	Promotes international harmonization of transportation of dangerous goods (TDG) regulations with US and international requirements.  Will facilitate trade, international and domestic co-operation.  Enhanced safety through a reduced number of incidents involving IBCs.  TDG regulations are adopted by provinces and territories through provincial and territorial legislation, thus providing uniform requirements across the country.	Canadian industry: Domestic regulations that reflect international requirements.  Canadians: Enhanced safety (new requirements will reduce potential leaks and spills).	Transport Canada (lead)  Provincial and territorial governments  Industry stakeholders  International organizations, including UNSCETDG and International Maritime Organization (IMO).	UNSCETDG to develop model regulations by July 2006 and seek international approval byJuly 2007.  Canadian regulations and standards to be developed to adopt the international agreement. Target is for regulations to be published in <i>Canada Gazette</i> by 2008.

Theme: Safety and Security

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Canada Shipping Act, 2001— Regulatory Reform:  Reduces more than 100 sets of regulations (dealing with commercial and recreational vessel use in Canadian waters) to approximately 35.  Moves from prescriptive to performance-based regulations.  Allows Transport Canada to concentrate limited inspection resources on areas that pose the greatest risk to marine safety.  Incorporates existing national or international standards by reference. Supported by a Regulations Query System (RQS) to search the Act and regulations for specific requirements. Introduces administrative monetary penalties, a modern non-criminal enforcement tool to increase compliance rates and designed to improve safety.	More efficient and modern regulations will enhance safety levels and improve compliance.  Contributes to more efficient regulatory process through concurrent management of issues.  Results in improved risk management through the establishment of a state-of-the art data and reference bank for inspectors and users.  Contributes to transparency and extensive stakeholder engagement.  Increases awareness by vessel owners and operators of marine safety regulatory obligations.  Facilitates international regulatory co-operation.	Internal and external stakeholders: Enhanced public safety and compliance ability. Ability to search online by type, size, voyage classification and topics of interest (such as safety, registration, licensing and construction).  Industry: Internationally compatible regulations will make it easier for industry to comply. Supports competitiveness.  Ship owners, operators and crews: Administrative monetary penalties will improve rate of compliance.  Canadians: Better protected marine environment.	Transport Canada (lead) Fisheries and Oceans Canada, Environment Canada (Parks Canada Agency).	New Canada Shipping Act, 2001 comes into force in fall 2006, along with Phase I of the regulations.  Phase II of the reform will begin in 2007 and includes those regulations that also require reform but do not need to be in place at the time that the new Act comes into force in 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Trilateral Automotive Partnership Council of North America (APCNA):  An industry-led council to promote greater compatibility in auto and auto parts regulations, standards and conformity assessment, while ensuring safety and environmental protection. Coordinates Canada, United States (US) and Mexico safety and environmental regulation development with United Nations (UN)/Economic Commission for Europe (ECE) Global Technical Regulations.  Part of the Security and Prosperity Partnership (SPP) signed by Canada, the United States and Mexico in March 2005. Commits the three countries to improve productivity through regulatory co-operation to generate growth, while maintaining high standards for health and safety.	A mechanism for the three governments to work with interested stakeholders to ensure competitiveness in the automotive sector.  Will improve North American coordination in safety and environmental regulation development.	Industry: Will ensure that existing and future mandatory regulations and testing procedures enhance trade and competitiveness. Will maintain or improve safety and environmental protection at a lower cost.  Consumers: Lower vehicle costs, while ensuring safety and environmental protection.	Industry Canada will work with regulatory departments such as Transport Canada and Environment Canada and the automotive sector.	Establish the council: target, fall 2005.  The council will make recommendations on key regulatory challenges. The North American Free Trade Agreement (NAFTA) Automotives Standards Council and the NAFTA Land Transportation Standards Subcommittee will then meet to consider the recommendations.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Reform of Canada's Insolvency System—Amendments to the Bankruptcy and Insolvency Act and Companies' Creditors Arrangements Act, along with the creation of a Wage Earner Protection Program Act:  Responds to the needs of the marketplace for a more efficient and certain bankruptcy and restructuring process. Will streamline the administrative process and allow more efficient processing of the more than 100 000 bankruptcies each year, while curbing the scope for abuse.  Will improve provisions to facilitate restructuring as an alternative to bankruptcy, thereby protecting jobs. Will provide better protection to workers in bankruptcy, by allowing wage claims and certain pension claims to have a higher priority level.	Will result in a more streamlined and efficient bankruptcy and insolvency process (e.g., less court time, more transparency, increased use of electronic filing and communications), while providing better protection for workers.  Will ensure that Canada's practices are in line with international guidelines for cross-border insolvencies.	Individuals and businesses: More predictable and efficient system that promotes restructuring as an alternative to bankruptcy.  Canadians: Better protection for workers.	Industry Canada (lead), Human Resources and Skills Development Canada.	Bill C-55, an Act to establish the Wage Earner Protection Program Act, to amend the Bankruptcy and Insolvency Act and the Companies' Creditors Arrangement Act and to make consequential amendments to other acts, was introduced on June 3, 2005.  Second reading completed. Referred to Standing Committee on Industry, Natural Resources, Science and Technology for review.  Once the legislation is adopted, a regulatory package will be developed to guide implementation.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Amendment to the <i>National Energy Board Cost Recovery Regulations</i> :  Initiated in March 2004 in response to concerns raised by segments of the electricity industry that the National Energy Board's (NEB) cost recovery process methodology is unfair because only electricity exporters pay cost recovery fees to the NEB.  Project objectives are to ensure that the NEB develops regulations that facilitate the recovery of costs while being equitable, efficient and financially predictable to the electricity industry.	Arose as a result of stakeholder input.  Involves close consultation with other federal and provincial regulatory agencies, as well as with the electricity industry.  Modifications ensure regulations are more responsive to a changing industry.	Electricity exporters: Cost recovery process adapted to today's electricity industry.  All industries coming before the NEB: Amended regulation that addresses gaps within the current regulation. Clear and effective cost recovery regulation.	NEB (lead). Treasury Board of Canada Secretariat, Natural Resources Canada (NRCan), Justice Canada.  Provincial energy departments  Electricity industry and related associations  Oil and gas pipeline industry and related associations (through the NEB Cost Recovery Liaison Committee).	Completed Phase I of consultation with industry and interested parties: June 2005.  Complete development of new cost recovery concept: December 2005.  Complete Phase II of consultation with industry and interested parties: March 2006.  Complete drafting of amendments to the National Energy Board Cost Recovery Regulations related to electricity industry: October 2006.  Tabling of proposed amendments to Parliament and Senate to comply with requirements of new User Fees Act. November 2006.  Commence formal regulation approval process: March 2007.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Canadian Offshore/Frontier Regulatory Reform Initiative (CORRI):  Under this initiative, the seven regulations governing the exploration for and production of petroleum in offshore and frontier areas under the purview of the NEB will be updated and streamlined.	Will result in a consistent regulatory regime for those working in any of Canada's offshore areas.  Will establish co-operation among federal departments and agencies, and provinces and territories.  Will incorporate international best practices into Canada's regulations.  Will contain more goal-oriented, as opposed to prescriptive, requirements.  Will result in more streamlined and modernized regulations.	Petroleum industry: More effective and efficient regulatory regime in Canada's offshore areas.  Provinces and territories: More attractive offshore energy industry.	Co-operative venture led by the following participants:  NEB (lead)  Canada–Newfoundland Offshore Petroleum Board  Canada–Nova Scotia Offshore Petroleum Board  Other participants include the following:  Federal departments:  NRCan  Indian and Northern Affairs Canada  Governments of the following provinces and territories:  Newfoundland and Labrador  Nova Scotia  New Brunswick  Prince Edward Island  Quebec  British Columbia  Yukon Territory  Northwest Territories	Amalgamation and updating of the <i>Drilling Regulations and the Production and Conservation Regulations</i> : to be ready for publication in <i>Canada Gazette</i> in early 2006.  Once this regulation is complete, work will begin on the <i>Installations Regulations</i> .  Anticipated completion date: 2009.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Natural Resources Regulatory Web Portal:  Single-window access on the Internet to information and resources on federal regulations that affect the natural resource sectors.  Will improve access to information, resources, and contacts regarding natural resources regulations from different federal government departments and agencies.	Improves coordination and co-operation within and among departments and agencies.  Embraces a government-wide approach to serving public needs and specific clients.  Will involve consultation with stakeholders on priorities regarding information provision and site components.	Public: Increased participation and confidence in Canada's regulatory regime. Increased awareness and understanding of natural resources regulations, tools, and resources. Enhanced compliance.  Small businesses: Less time to find relevant information, more incentive to undertake new initiatives.  Natural resource sectors and related industry: Easier identification of relevant requirements and support tools. Easier compliance.  Department and regulators: Potential support for issue identification and policy development. Information sharing.  Investors: Increased understanding and less uncertainty.	NRCan (lead) Other departments and agencies participate through an interdepartmental advisory group.	Consultation and content development: target, fall 2005.  Refinement of content and development/testing of site: target, winter 2006.  Outreach and site launch: target, spring 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Implementation of Inter-American Telecommunication Commission (CITEL) Mutual Recognition Agreement (MRA) on Conformity Assessment:  Easier market access by having telecommunications equipment testing and certification bodies in an exporting partner country recognized to test and certify to an importing partner country's requirements.  Implementation of Canada, US and Mexico portion of the Agreement is part of the SPP signed by Canada, the United States and Mexico in March 2005.	Aligns regulatory environment with marketplace.  Reduces cost and administrative burden to business by streamlining testing and certification processes and reducing the amount of duplicate testing between countries.  Previously, a product had to be tested and certified by the importing country in addition to the test conducted within the exporting country (as part of the manufacturing process). Testing and certification can now be carried out by a recognized body in the exporting country, thus reducing the cost and inconvenience of testing and certifying the equipment abroad.	Equipment suppliers: Reduced time and costs associated with duplicate testing or conformity assessments of certain tele- communications equipment before it can be sold in Canada, the United States and Mexico, as well as in other participating MRA partners in the Americas. Will remove a significant non-tariff barrier to trade. Consumers: Possible reduced costs and access to new products.	Industry Canada  US Department of Commerce, Mexico—Ministry of Communications and Transports and Ministry of the Economy.	Implementation of Phase I (acceptance of test results from recognized laboratories): Completed in United States and Canada in June 2005.  Mexico implementation to begin June 2006.  Implementation of Phase II (acceptance of product certification from recognized certification bodies): United States and Canada, after June 2007; Mexico, after 2008.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Organic Product Certification Standards:  Regulations to introduce a national organic standards and certification regime for food to protect consumers and facilitate international market access.  The federal government will be established as the overall competent authority for the Canadian Organic Regime. Existing private and public sector certification bodies and accreditation agencies will be integrated.  The European Union (EU) requires that countries exporting organic foods to EU members be on a third-country equivalence list. To be placed on this list, third countries must be recognized as having rules of organic production and a system of inspection equivalent to those in the European Union. These requirements could not be met within Canada's current voluntary system.	Involves a high degree of federal-provincial and industry co-operation.  Builds consumer confidence in organic food production system and allows them to make more informed choices.  Compatible with international practices and standards.  Existing third-party mechanisms could be responsible for system integrity and on-farm verification, rather than direct government delivery. Consistent with international models.	Consumers: Enhanced consumer protection from fraudulent practices and a fair market place. Industry: Increased domestic market acceptance and international access.	Canadian Food Inspection Agency (CFIA) (lead), Agriculture and Agri-Food Canada (AAFC) and International Trade Canada. Canadian Government Standards Board is developing the National Organic Standard.  Since the interdepartmental Organic Task Force began work in November 2004, there have been 106 meetings throughout Canada with organic producers, processors, certification bodies, accreditation bodies, importers, distributors, provincial governments, and other stakeholders, including consumers.	Stakeholder consultation has been ongoing and will continue as National Organic Standard is finalized and proposed regulations are published.  Publication in <i>Canada Gazette</i> Part I: target, March 2006.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Fair and Ethical Trading— Fruits and Vegetables:  Review of the Licensing and Arbitration Regulations and the Fresh Fruit and Vegetable Regulations, in consultation with Canadian stakeholders and international partners. Will strengthen the current Canadian regulatory regime and inspection services governing product grade and trading standards, dispute resolution, and fraud prevention for perishable agricultural commodities (fruit and vegetables).  Responds to concerns within the fresh fruit and vegetable industry in Canada that unethical business practices in a market dealing with perishable products is eroding confidence in the industry, that Canadian fresh fruit and vegetable grade standards may not reflect current marketing practices, and that delivery of CFIA destination inspection services is untimely.  A Smart Regulation regulatory review pilot project.	Strengthens existing regulatory co-operation among NAFTA partners by increasing harmonization of product grade standards and trade practices within North America.  Strengthens co-operation among federal departments and agencies.  Improves service standards for product inspections.  More efficient regulatory management and change process.  Increases stakeholder involvement and leadership in regulatory management process and enhances transparency and accountability of regulatory system.	Producers and shippers of fruits and vegetables: Fewer losses and increased returns associated with improved trading environment.  Fruit and vegetable wholesalers and retailers: Predictable and reliable supply of safe, high-quality fruits and vegetables and access to enhanced destination inspection service.  Consumers: Reliable and affordable supply of safe, high-quality fruits and vegetables.	CFIA (lead), AAFC.  Canadian, US and Mexican industry and producer associations, Fruit and Vegetable Dispute Resolution Corporation, US Department of Agriculture.	Initial review of trade practices and identification of options for addressing problems: March 2006.  Implementation of enhanced CFIA destination inspection service: target, 2005–2007.  Harmonization of Canada–US grade standards for range of fruit and vegetable products: target, 2005–2010.  Review of regulatory framework and preliminary identification of areas for improvement and consultation: target, March 2007.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Fertilizer and Supplements Regulation:  To improve the identification, assessment, mitigation and management of risk in relation to the efficacy, safety and labelling of fertilizer and supplement products. To propose changes to the product registration process.  A Smart Regulation regulatory review pilot project.	Reduced regulatory compliance burden and facilitation of a more rapid and efficient regulatory process as a result of more responsive program design, systematic regulatory review, development and maintenance of service delivery standards, and implementation of alternative delivery mechanisms.  Improved international and federal-provincial regulatory co-operation.  Establishment of a permanent consultative framework will result in strengthened coordination among federal departments and agencies, increased transparency, and improved stakeholder engagement in regulatory process.	General public: Increased assurance of safe, effective, properly labelled fertilizer and supplement products.  Fertilizer and supplement industry: Increased predictability and efficiency of regulatory regime.  Agricultural producers: Improved access to reliable and safe fertilizer and supplement production inputs.	CFIA (lead), Health Canada.  Industry associations, consumer groups, provincial and municipal governments.	Initial phase of development of a strengthened permanent consultative framework: March 2006.  Initial consultation on regulatory amendment to increase length of product registration: March 2006.  Initial phase of program restructuring: July 2006.  Initial review of alternative delivery options for Canadian Fertilizer Quality Assurance Program: November 2006.  Consultation and development of proposed new product registration service standards: March 2007.

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Seed Regulations:  To increase the ability of the variety registration system to respond to evolving agri-food sector needs.  Designed to strengthen the regulatory framework and facilitate the modernization of regulations, programs and associated consultative processes governing, in particular, the production, import and sale of seed.  A Smart Regulation regulatory review pilot project.	Improved international and federal-provincial regulatory co-operation, and better coordination among regulatory departments and agencies through a strengthened regulatory discussion framework.  Enhanced participation in the regulatory process by stakeholders and citizens, through engagement in a consultative forum.  Reduced regulatory compliance burden in certain areas by simplifying and introducing more flexibility in the variety registration system.  Faster and more efficient regulatory process due to consensus-driven consultation process and modernization of seed regulations.	Public: Increased transparency and confidence in regulatory system.  Seed industry: Increased predictability, responsiveness and efficiency of regulatory regime and higher rate of product innovation and commercialization.  Agricultural producers: Increased participation in seed regulatory system and improved access to seed from a wider range of crop varieties.	CFIA (lead), AAFC, Canadian Grain Commission.  Industry associations, agricultural producer groups, civil society.	Complete initial development of strengthened, permanent consultative framework: target, March 2006  Complete pre-consultation on proposed changes to variety registration system: target, March 2006.  Introduce and implement changes to variety registration system: target, March 2007.  Review and identify additional priority areas for improvement in seed regulatory system: ongoing.

Theme: Aboriginal Prosperity and Northern Development

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Proposed First Nations Commercial and Industrial Development Act:  To enable the federal government, at the request of individual First Nations, to make regulations that address regulatory gaps for proposed on-reserve projects.  Regulations would replicate provincial regulations pertaining to environmental protection and health and safety on a project-specific basis applicable to similar off-reserve projects, and apply to specified reserve lands and activities. These regulations would provide certainty, thereby strengthening economic development on reserves.	Addresses a regulatory gap. (In many cases, existing federal laws do not meet the needs of such projects. However, extensive provincial regulations that apply to similar off-reserve projects do not apply on reserves for constitutional reasons.)  Will build on existing provincial infrastructure for inspection and enforcement based on agreements with provinces and First Nations.  Regulations will be developed at the request of individual First Nations and will be project-specific and apply to specified reserve lands.	First Nations: Cornerstone of Canada's commitment to provide First Nations with the tools for economic development. Closes the gap with other Canadians in terms of socio-economic indicators, such as health and income.  Industry: Greater certainty for investors and partners for on- reserve economic development through a regulatory environment that is familiar.  Provinces: Creates a level playing field with similar projects within a province.  Canadians: Strengthens economic development on reserves and creates opportunities off reserves, while ensuring environmental and public health and safety.	Indian and Northern Affairs Canada (INAC) (lead)  • Environment Canada  • Input from First Nations in Alberta, Ontario, British Columbia, and Saskatchewan  • Provinces of Alberta and Ontario	Legislation: To be introduced in fall 2005.

Theme: Aboriginal Prosperity and Northern Development

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
The Assessable Activities, Exceptions and Executive Committee Projects Regulations:  Developed pursuant to the Yukon Environmental and Socio-Economic Assessment Act. Will identify the types of projects that will be captured or excluded from environmental assessment (EA) in the Yukon. Created as an obligation of the Yukon land claims agreements.  Involves the creation of a multipartite working group to consult and negotiate provisions.	Developed by consensus in partnership with the federal government, territorial government, and Yukon First Nations. Embodies the "one project, one assessment" principle, reducing duplication and uncertainty.  Brings together both federal and territorial EA jurisdictions.	Industry and public in Yukon: An effective and efficient environmental and socio-economic assessment regime that respects federal obligations under land claims. Clarifies which development projects will be captured or exempted from EA, providing certainty, consistency and an effective use of funding resources.	INAC (lead) in close collaboration with other federal departments such as Fisheries and Oceans Canada, Transport Canada, and Environment Canada.  Other participants include the Canadian Environmental Assessment Agency (CEAA), the territorial government, and the Council for Yukon First Nations.	Final approval and publication in Canada Gazette Part II: target, December 2005.

Theme: Aboriginal Prosperity and Northern Development

Activity	Why Is It Smart?	Who Benefits and How?	Participants	Implementation Status
Proposed Nunavut Resource Management Act:  Will establish the environmental assessment (EA) and land-use planning framework for Nunavut.  Final legislative obligation under the Nunavut Land Claims Agreement.	Will provide certainty, clarity and consistency to land use planning and EA in Nunavut.  Will establish when federal or territorial EA processes apply.  Allows the inclusion of more details about the operation of the regime than is currently provided in the land claim, including details about liabilities, timelines, inclusion and exclusion of certain projects, and so on.  Will be developed by a multipartite legislative working group involving Canada, Nunavut, Nunavut Tunngavik Inc. (NTI), the Nunavut Impact Review Board, and Nunavut Planning Commission.	Industry and public of Nunavut: Will encourage development opportunities and provide a clearer, more consistent and predictable resource regime, while protecting the natural environment.	INAC, CEAA.  In partnership with Nunavut and NTI, consultations will be carried out with major industry organizations and other key stakeholders.	Legislation: Expected to be ready for tabling in December 2006.  Consultation will be ongoing throughout development of the bill.

# **Completed Initiatives**

The following initiatives, first introduced in the March 2005 edition of this report, are complete and currently being implemented:

- 1. **Cosmetic Ingredient Labelling:** Regulations will come into force in November 2006, following a two-year implementation period to allow industry to use existing stock and prepare new labels for products. As a result of this initiative, consumers and health care practitioners will know all ingredients used in cosmetic products. As well, adverse reactions will be treated more effectively.
- 2. Environmental Assessment MOUs for East Coast Offshore Oil and Gas Development: MOUs have been signed, facilitating implementation of a streamlined process for the next large-scale offshore development project in Nova Scotia or Newfoundland and Labrador. This initiative will eliminate duplication and delays, and will result in a more competitive investment climate in offshore industries.
- 3. Amendments to Canada Business Corporations Regulations, 2001: Regulations were brought into force in March 2005 to enable federal corporations governed by the US Securities and Exchange Commission to prepare and audit their financial statements using generally accepted US accounting principles. This initiative will reduce overlapping requirements and eliminate the need for federally incorporated businesses (that are subject to American securities regulation) to prepare and audit two sets of financial statements.