

# UNITED STATES-CANADA REGULATORY COOPERATION COUNCIL

Joint Action Plan

DECEMBER 2011



# Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation

Today, President Barack Obama and Prime Minister Stephen Harper have directed the creation of a United States—Canada Regulatory Cooperation Council (RCC), composed of senior regulatory, trade, and foreign affairs officials from both governments. In recognition of our \$1 trillion annual trade and investment relationship, the RCC has a two-year mandate to work together to promote economic growth, job creation, and benefits to our consumers and businesses through increased regulatory transparency and coordination.

They have directed that the first meeting of the RCC be convened within 90 days by the relevant agencies in the United States and Canada.

The President and the Prime Minister have taken this initiative because they believe that their citizens deserve smarter, more effective approaches to regulation that enhance the economic competitiveness and well-being of the United States and Canada, while maintaining high standards of public health and safety and environmental protection. Improving regulatory cooperation and adopting compatible approaches will lead to greater prosperity on both sides of the border and will in no way diminish the sovereignty of either the United States or Canada or the ability of either country to carry out its regulatory functions according to its domestic and legal policy requirements.

The President and the Prime Minister both recognize the crucial importance of such regulatory cooperation as the U.S. and Canadian economies pull out of the recession and confront the challenges of improving productivity and keeping a competitive edge.

They also believe that regulatory cooperation can spur economic growth in each country; fuel job creation; lower costs for consumers, producers, and governments; and particularly help small and medium-sized businesses. The United States and Canada intend to eliminate unnecessary burdens on cross-border trade, reduce costs, foster cross-border investment, and promote certainty for businesses and the public by coordinating, simplifying and ensuring the compatibility of regulations, where feasible.

The United States and Canada are committed to working through the RCC to provide early notice of regulations with potential effects across our shared border, to strengthen the analytic basis of regulations, and to help make regulations more compatible.

Building on ongoing cooperation, both countries intend to work through the RCC to determine sectors on which to focus its work that are characterized by high levels of integration, significant growth potential, and rapidly evolving technologies.

Both countries are committed to evidence-based, predictable, cost-effective regulatory approaches carefully targeted to enable businesses to continue to innovate and grow.

The President and the Prime Minister believe that the United States and Canada must work together to make their economies stronger and more competitive, while meeting their fundamental responsibilities to protect the safety and welfare of their citizens.



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# Background

On February 4, 2011, President Barack Obama and Prime Minister Stephen Harper announced the creation of the United States-Canada Regulatory Cooperation Council (RCC) to increase regulatory transparency and coordination between the two countries.

Regulation plays an important role in both our countries. Effective regulations protect our health, safety, and the environment while supporting growth, investment, innovation, and market openness. The United States and Canada each have well-developed, independent regulatory regimes and regulatory departments and agencies with experience, expertise, and skill in their respective fields, that support each of our domestic and legal policy requirements. While our regulatory systems are very similar in the objectives they seek to achieve, there is value in enhancing the mechanisms in place to foster cooperation in designing regulations or to ensure alignment in their implementation or enforcement. Unnecessary regulatory differences and duplicative actions hinder cross-border trade and investment and ultimately impose a cost on our citizens, businesses, and economies. Given the integrated nature of our economies, greater alignment and better mutual reliance in our regulatory approaches would lead to lower costs for consumers and businesses, create more efficient supply chains, increase trade and investment, generate new export opportunities, and create jobs on both sides of the border.

The RCC will undertake efforts to better align the regulatory environment between the United States and Canada through a variety of tools such as enhanced technical collaboration, mutual recognition of standards, and joint work sharing, in an effort to address root causes of regulatory misalignments, develop lasting solutions, and avoid future misalignments from developing. This initial Joint Action Plan seeks to foster new approaches to regulatory alignment and serve as a template for future efforts at United States-Canada coordination. Council members agreed to Terms of Reference<sup>1</sup>, which established the mandate, principles, and structure of the RCC and will guide the work of the RCC throughout its mandate. Nothing in this Joint Action Plan is intended to give rise to rights or obligations under domestic or international law.

\* 1 \*

<sup>1.</sup> The RCC's Terms of Reference can be found at <a href="www.borderactionplan-plandactionfrontalier.gc.ca/psec-scep/">www.borderactionplan-plandactionfrontalier.gc.ca/psec-scep/</a> rcc\_tor-mandat\_ccr.aspx?lang=eng and <a href="www.whitehouse.gov/omb/international\_regulatory\_cooperation">www.whitehouse.gov/omb/international\_regulatory\_cooperation</a>.



# Stakeholder Engagement

Stakeholder input was key in developing this initial Joint Action Plan, which represents a first set of actions and initiatives that will begin the process of developing more closely aligned regulatory systems between the United States and Canada. Working closely with Federal regulators on both sides of the border, stakeholder input was considered according to a number of criteria: potential for tangible benefits to businesses or consumers; support from impacted stakeholders; opportunity for a lasting solution to the immediate irritant; feasibility of delivery within a 2-year timeframe; potential to enhance regulatory efficiency while preserving regulatory objectives; and potential to serve as a model to develop transformational tools or mechanisms for durable regulatory alignment that could be applied across sectors.

To help guide the development of the Joint Action Plan, the United States and Canada reached out to a wide range of stakeholders for input. This included citizens, companies and industry groups, civil society, and provincial and territorial governments. Feedback through this public consultations process provided valuable input on priority areas where meaningful progress could be made in this initial phase.

# The Joint Action Plan

This initial Joint Action Plan is an important step in an ongoing process of regulatory cooperation between the United States and Canada. Work that will be undertaken in the areas of agriculture and food, transportation, environment, and health and consumer products is an important step in building bridges that will provide direct, tangible benefits to American and Canadian consumers and businesses through easier trade flows, lower production costs, streamlined regulatory compliance, reduced testing costs, greater consumer choice, and a better climate for business and economic growth on both sides of the border without compromising the consumer, public health, and environmental protections citizens on both sides of the border rightly expect and have grown to trust. The RCC will focus its capacity and efforts on issues identified in this plan while also looking toward the longer term—identifying initiatives that could be included in subsequent phases of work—for example extending collaboration on emissions standards for heavy duty vehicles.

In developing this initial Joint Action Plan, the RCC was guided by of the following key principles, as set out in its Terms of Reference:

- Each country will maintain its own sovereign regulation—mutual reliance on the other country's system to inform one's own decisionmaking, and closer alignment of existing Federal regulatory systems, consistent with domestic law, will be the focus.
- Regulatory outcomes for consumer protection, health, safety, security, and the environment will not be compromised.
- New regulatory systems will be designed with the goal of achieving regulatory alignment, to the
  extent feasible and appropriate. Regulatory alignment will be sought for all future United StatesCanada regulatory system development—with differences existing only where necessary and with
  the impacts considered.
- The role of the RCC will be one of broad engagement, bilateral and horizontal coordination, idea generation and challenge. Efforts towards regulatory alignment will be conducted by lead departments and agencies, under broad guidance from the RCC and in consultation with impacted stakeholders. The goal is to align existing Federal regulatory systems or, absent such alignment, encourage the adoption of other measures that make it easier to conduct business between the two countries, where such efforts are feasible and appropriate and consistent with other RCC principles.
- In addition to resolving existing unnecessary divergences, mechanisms to facilitate and secure
  future alignment will be developed. Transparency and early engagement between countries and
  with stakeholders will underlie these efforts.
- Opportunities will be pursued that provide benefits to both the United States and Canada.

In developing and implementing the initiatives identified in this Joint Action Plan, officials in both countries are encouraged to challenge the status quo, create new synergies and opportunities for alignment, and look at systemic regulatory changes that will result in permanent change—with alignment as a key objective in future regulatory work.

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This initial Joint Action Plan has been designed to focus on a limited number of initiatives where meaningful and lasting progress can be made in the near term. As a result, there were a number of suggested initiatives that were considered but not included in the initial Joint Action Plan. The RCC will continue to examine these suggestions as it develops areas for future work. In some cases, solutions that are implemented as part of this Joint Action Plan may be helpful in solving issues in these other areas.

In establishing its initial Joint Action Plan, the RCC and regulatory departments have faced challenges in measuring the potential economic benefits related to regulatory alignment initiatives. In order to inform its future work and assist in the identification of possible opportunities for realignment that will generate benefits, the RCC will work alongside regulatory departments as they implement the Joint Action Plan items. In this regard, these initiatives can serve as practical examples to inform the development of tools and criteria related to assessing regulatory alignment benefits by the RCC.



# Joint Action Plan Issues

The Joint Action Plan sets out 29 initiatives where the United States and Canada will seek greater alignment in their regulatory approaches over the coming 2 years. The following section highlights the areas and initiatives which have been identified for initial focus.

# **Agriculture & Food**

Agriculture and food-related industries are backbones of the United States and Canadian economies—feeding Canadians and Americans while providing important rural jobs. In 2010, with \$33 billion in total bilateral trade in agricultural products, Canada purchased approximately 13 percent of U.S. exports, while nearly one-fifth of U.S. agricultural imports came from Canada. Bilateral economic cooperation builds on our respective efficiencies and creates a more competitive and integrated agri food sector—not only do the United States and Canada trade food products, but both countries also rely on each other for inputs into the agricultural production process. This bilateral trade provides people in both countries with increased employment opportunities, consumers on both sides of the border with a greater variety of safe, healthy, and wholesome food products, and agricultural producers and food processors with a larger and more diversified market in which to operate.

# A. Food Safety

# What is the opportunity?

The United States and Canada have very robust food safety systems to safeguard food in order to protect consumers and contribute to the success of the sector. This, combined with ongoing close collaboration and an acknowledgement between American and Canadian regulatory organizations of the level of United States-Canada integration within the sector, has driven a commitment to increase collaboration and acknowledge the rigor of each other's controls with a view to making a safer, more secure food supply while facilitating agri-food trade between the two countries.

Food produced under the regulatory systems in both countries is some of the safest in the world, and it should usually not be necessary to apply additional inspection or testing requirements, simply because it is crossing the United States—Canada border. Acknowledging the high food safety standards applied on both sides of the border provides an opportunity to focus on areas of higher risk, while removing unnecessary burdens on the food production sector in the United States and Canada where risk is generally lower. The work under this Joint Action Plan will focus on leveraging each other's expertise and building our food safety systems upon the same principles as efforts are made to improve them; relying primarily on the strength of each other's systems to ensure food produced in that country is safe; and minimizing the unnecessary duplicative verification activities and requirements imposed on products flowing between the United States and Canada. While each country autonomously sets its own standards, and there can be legitimate reasons for differences between the United States and Canada, wherever possible, efforts should be focused on alignment.

# **Joint Action Plan Initiatives**

- Develop common approaches to food safety, in light of food safety modernization efforts in both
  countries, to jointly enhance the safety of the United States—Canada food supply and minimize the need
  for routine food safety surveillance inspection activities in each other's country (applies to products
  within the mandates of both the U.S. Food and Drug Administration and the Canadian Food Inspection
  Agency).
- Enhance **equivalence agreements for meat safety systems** to streamline, simplify, and, where possible, reduce import and administrative procedures, while maintaining public health outcomes.
- Establish mutual reliance on jointly acceptable food safety laboratory recognition criteria, test results, and methodologies to ensure food safety laboratory testing conducted in one country is acceptable to regulators in both countries and facilitate cross-utilization of laboratory results by industry and regulators (applies to products within the mandates of both the U.S. Food and Drug Administration and Canadian Food Inspection Agency).
- Streamline the **certification requirements for meat and poultry** including, where possible, the reduction or elimination of redundant certification, data elements, and administrative procedures for shipments flowing between the United States and Canada.

# What are the benefits?

Focusing American and Canadian efforts on enhanced collaboration in food safety and activities to allow for assessment and possible recognition of system comparability would benefit consumers and businesses by enhancing food safety outcomes in both countries while minimizing potential impacts on trade. Through reliance on the controls and mitigation measures rooted in each other's systems, the United States and Canada can work towards agreement that a product coming from the other country is in compliance with the importing country's requirements and should not routinely trigger additional regulatory action. Reducing the duplicative verification activities on foods coming from lower-risk situations would benefit regulatory agencies on both sides of the border, as well as consumers, by allowing food safety protection resources to be targeted at situations where the risk is higher. These initiatives would also help prevent unnecessary differences in regulatory measures and costly trade irritants in the future, thus facilitating movement of goods between countries and minimizing costs ultimately borne by consumers.

# **B. Agricultural Production**

# What is the opportunity?

United States and Canadian regulatory requirements and approval processes for agricultural products such as veterinary drugs and crop protection products (e.g., pesticides) are already highly aligned. However, further symmetry could promote greater work sharing between the two countries, contributing to more simultaneous access for producers to the most effective production tools. In addition, collaboration in this area would minimize discrepancies between American and Canadian established maximum residue limits/tolerances of pesticides and veterinary drugs when there is no public health need for such differences.

Annually, plant pests, diseases, and invasive alien species cause billions of dollars in direct losses, control costs, production costs, and lost market opportunities for the United States and Canada. A perimeter approach to collectively protecting United States—Canada territory from the unintentional introduction of these organisms via cross-border movement of plants and plant products would maximize the efforts currently underway in both countries. On the animal health side, each country has measures in place to prevent the introduction and spread of animal diseases to and within their own territory; however differences in how these measures are applied in the event of a foreign animal disease outbreak in a trading partner can create significant trade disruptions. As an example of the impact disease can have, the detection of Bovine Spongiform Encephalopathy (BSE) in North America severely hindered trade in sheep, goats, cattle, and their products, resulting in billions of dollars worth of lost trade and other impacts.

## **Joint Action Plan Initiatives**

- Further align crop protection product (e.g., pesticides) approvals and establishment of maximum pesticide residue limits/tolerances in both countries.
- Further align marketing application submission and review processes for veterinary drugs, including efforts to establish identical maximum drug residue limits/tolerances in both countries.
- Develop a **perimeter approach to plant protection** with a view to leverage each country's efforts to mutual advantage and, where possible, streamline certification requirements for cross-border shipments.
- Work towards a common approach to zoning of foreign animal diseases.

# What are the benefits?

Increased regulatory cooperation on agricultural products will contribute to increased quality, value, and quantity of products grown and raised in the United States and Canada by allowing greater access for producers to the most effective tools available to manage production problems. Furthermore, these efforts will help to align maximum residue limits/tolerances of pesticides and drugs, facilitating trade in a wider variety of agricultural commodities, and providing consumers in both countries with more choice and predictability at the grocery store. In addition, further alignment will enable new and continued work-sharing and information-sharing between American and Canadian regulators, allowing them to benefit from expertise housed in each country.

It is widely estimated that, in Canada alone, the damage resulting from past introductions of harmful invasive plant pests on Canadian agricultural crops and forestry is \$7.5 billion annually. The value of similar losses to U.S. agricultural crops and forestry is estimated at \$24 billion annually. Combining efforts on plant protection towards a perimeter approach would help avoid costs associated with damage caused by introduction and spread of harmful plant pests, diseases and invasive alien species. A partnered perimeter approach would minimize introductions from third countries and instil confidence in the freedom of products from plant pests, diseases, and invasive alien species coming from the United States

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and Canada, thus protecting trade relationships. Furthermore, it would reduce the regulatory activities required at the United States—Canada border to ensure species of concern are not being introduced bilaterally. In reaching agreement on zoning for foreign animal diseases, the United States and Canada can ensure that both countries are collectively protected from disease but bilateral trade can continue from areas that are shown to remain disease-free following an outbreak, giving producers a level of predictability with regard to approach by the two countries. Furthermore, a common framework could be advocated internationally to encourage other trading partners to apply scientifically valid approaches to zoning for foreign animal diseases.

# C. Marketing

# What is the opportunity?

Both the United States and Canada recognize the need for fair and ethical trading practices within the agriculture and food sector—both for consumers and companies. Differences in meat cut nomenclature systems create confusion for consumers and additional costs for firms selling into both the American and Canadian markets. A common, United States—Canada approach would correspond with the integrated nature of the American and Canadian meat sectors.

#### **Joint Action Plan Initiatives**

- Create a common **meat cut nomenclature** system and regulatory alignment tool to jointly maintain the system.
- Develop comparable approaches to **financial risk mitigation tools** to protect U.S. and Canadian fruit and vegetable suppliers from buyers that default on their payment obligations.

The American and Canadian produce industries share a common market and are complementary, providing a wide selection of fruits and vegetables for American and Canadian consumers. The provision of financial risk mitigation options for companies engaged in bilateral trade in perishable produce would contribute to the fair and effective functioning of the bilateral horticultural marketplace.

## What are the benefits?

A common approach to naming meat cuts would allow for innovation and product development, and eliminate costs associated with inventory production and maintenance for firms selling into both markets. It would provide consumers with a simple information system to allow them to make price comparisons and cooking decisions across both countries with no impact on food safety.

The majority of growers and shippers of produce are small- and moderate-sized businesses which depend on prompt payment to meet their financial obligations. Having comparable financial risk mitigation tools available to these businesses in both the United States and Canada would level the playing field by minimizing the risks for shippers in the bilateral marketplace.

# **Transportation**

Transportation plays a crucial role in both of our economies. Sharing the longest land border in the world, with common access to three oceans and to the Great Lakes and St. Lawrence Seaway, the United States and Canada depend on safe, secure, and efficient transportation systems for the movement of goods and people. The transportation system, comprised of roadways, rail lines, airways, and waterways employs more than 11 million people in the United States and Canada and is responsible on a yearly basis for the movement of more than 11.1 billion tonnes of freight, valued at more than \$7 trillion. More than \$1.6 billion worth of goods cross daily between both countries. In order to ensure economic growth for the United States and Canada, and the continued success of our strong bilateral trade and shared prosperity, there is a natural incentive for the United States and Canada, two of the most highly integrated economies in the world, with over 160 million border crossings each year, to collaborate very closely on transportation regulatory issues.

# A. Surface (Road & Rail)

# What is the opportunity?

Surface transportation impacts almost all aspects of the American–Canadian economic partnership and the benefits of greater regulatory cooperation in this area will be far-reaching. There is an opportunity to develop an institutionalized mechanism to ensure ongoing alignment between both countries to minimize the occurrence of divergent new standards.

The automotive industry has been one of the most important contributors to our North American economy, growing into a large, modern, efficient, and productive engine of economic strength. By working together as an integrated industry, the American and Canadian auto sector has become a powerful North American market, which accounts for the production of over 16.5 million vehicles annually, and is responsible for 500,000 direct and indirect jobs in Canada and 3.2 million in the United States. Although motor vehicle standards are generally aligned between the two countries, differences in some standards result in duplicative testing and increased costs for prototypes, which may negatively affect the competitiveness of this industry on the world stage. Regulatory alignment offers a unique opportunity to improve our standards development process which would help to ensure that a collaborative approach is implemented for both existing and future regulations, taking into account each country's safety risks and safety needs.

Freight rail plays a major role in both the American and Canadian economies by sustaining our domestic and international trade, generating more than \$265 billion in total economic activity, and by supporting more than 1.2 million jobs in the United States. Americans and Canadians depend on a rail system that can transport freight to markets reliably and quickly. In 2010, American and Canadian railways carried more than 1.5 million intermodal containers and trailers across our common border, illustrating the importance of rail corridors as a vital link in the supply chain. Harmonization of regulatory regimes in the rail sector will enhance the efficiency and safety of this vital mode of transportation. Our shared network of ports and rail and road connections allow the flow of cargo across the United States and Canada. Shippers everywhere rely on rail transportation as an important supply chain partner. It is therefore opportune for Canada and the United States to enhance their close working relationship.

#### **Joint Action Plan Initiatives**

- Ensure greater alignment of **existing motor vehicle safety standards**, notably by developing a lasting approach to align and adopt motor vehicle standards that take into account each country's safety risks and needs.
  - Work together towards further alignment of the side impact and ejection mitigation standards.
  - Study areas where standards are not aligned (identification of controls and displays; lighting—daytime running lamps; and occupant protection) with a view to determine where greater collaboration in the standards development process could have been applied to have avoided this divergence, and adapt and fix standard setting processes accordingly.
- Jointly review and establish a common collaborative regulatory standard setting agenda for all **new motor vehicle safety standards** (e.g., rear camera, electric and alternative energy vehicles, quiet cars).
- Work together on the development of regulations and standards to fully support the integration of **intelligent transportation systems**.
- Align rail safety standards and establish a joint mechanism to conduct periodic review of regulations.

#### What are the benefits?

Greater harmonization of vehicle safety standards will reduce production and design costs, facilitate the considerable cross-border trade in vehicles and parts, offer greater selection and lower costs to consumers. These benefits will ultimately make the North American automobile manufacturing sector more competitive on the world stage.

Coordinated standards for Intelligent Transportation Systems will promote the seamless development of tomorrow's vehicle technologies and infrastructure and allow the two countries to be global leaders in this area.

Aligning the rail safety regulations will help to enhance the safety, efficiency and reliability of the rail system and ensure its continuance as a vital mode of transportation well into the 21<sup>st</sup> century.

# B. Marine

# What is the opportunity?

The United States and Canada share common waterways that are central to our quality of life and economic prosperity. The marine industry provides for the movement of goods by water to important landside services including critical connections to road and rail. The overall economic success of both countries depends on efficient and reliable, safe and secure marine transportation routes connecting our continent to the world. In order to facilitate the movement of goods and people, addressing regulatory and operational issues in a coordinated manner is crucial.

On a yearly basis, over 2.5 billion tons of cargo are handled by American and Canadian ports. Ferries in United States and Canada provide an essential mode of transport, moving more than 178 million passengers every year. Marine transportation also plays a key role in tourism. Every year, the United States and Canada receive more than 7 million cruise ship passengers, generating billions of dollars in both economies. Alignment of regulatory regimes will help to ensure that marine transportation remains an engine of economic growth and a source of employment for millions of North Americans.

#### **Joint Action Plan Initiatives**

- Establish a United States-Canada safety and security framework and arrangement for the **St. Lawrence Seaway and Great Lakes system** in order to align regulatory requirements.
- Align the **marine transportation security requirements** to prevent duplication of services and remove impediments to cross-border operations and incorporate the ability to use Alternative Security Arrangements in the Canadian regulations.
- Align **recreational boat manufacturing** standards and develop a proposal for aligning the monitoring and compliance regimes.
- Move to a common standard for **lifejackets**, and consider developing mutual recognition arrangement(s) for other **marine safety equipment**.

#### What are the benefits?

Greater collaboration in the development and implementation of our respective regulatory regimes will contribute to ensure that this transportation sector remains a safe, secure, efficient, and sustainable mode of transport. Waterborne cargo alone provides employment for more than 13 million American and Canadian citizens. Harmonizing our regulatory regimes will facilitate the flow of bilateral trade and will help to contribute to the competitiveness of the North American marine shipping industry by allowing our goods to be shipped to markets in the most efficient and cost-effective way possible.

# **C. Other Transportation Issues**

# What is the opportunity?

There are other transportation issues where greater regulatory alignment could help contribute to the competitiveness of business operations, the facilitation of cross-border trade, and help both countries adopt a proactive joint approach with new emerging technologies.

Currently, the dangerous goods "means of containment" standards vary between the United States and Canada. Different ways of packaging our dangerous goods represents an impediment for shippers on both sides of the border since they have to deal with two different sets of requirements. Both countries will explore ways to enhance reciprocity with respect to recognition of standards for means of containment, as well as with respect to recognition of special permits and approvals, which may result in reduced costs for approvals, product testing, and all costs associated with export certification.

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The same concept applies for unmanned aircraft systems—aircraft weighing less than 35 kg used for flight testing, aerial photography, filming for television documentaries, or offshore geophysical surveys. The United States and Canada can jointly undertake to develop and adopt common standards for unmanned aircraft systems and establish a mechanism to share regulatory experiences, with a view to aligning regulatory approaches.

#### **Joint Action Plan Initiatives**

- Work to better align American and Canadian standards on the **containment of dangerous goods**.
- Establish a mechanism to share experiences on regulations related to **unmanned aircraft systems**, with a view to aligning regulatory approaches.

# What are the benefits?

An aligned system for the packaging of dangerous goods would facilitate product movement across borders and reduce costs associated with having two systems. Harmonization of standards in this area would allow industry to no longer have to use two different types of packaging to transport goods across the border.

Aligning American and Canadian requirements for unmanned aircraft systems would allow both countries to gain safe and routine access to airspace without restricting other airspace users.

# **Health and Personal Care Products and Workplace Chemicals**

Effective regulation of health and personal care products, as well as workplace chemicals, minimize health risks while maximizing health benefits and safety to citizens. Both the United States and Canada have among the highest standards of health and safety in the world, founded on strong and effective procedures for the development, assessment, and marketing authorization (approval, licensing, and/or and registration) of health and personal care products and the classification of workplace chemicals.

# What is the opportunity?

The United States and Canada have a long history of working collaboratively to address and advance common health related interests through both formal and informal activities. Nevertheless, despite the integration of the American and Canadian markets—and our generally similar risk tolerances—subtle regulatory differences can hinder two-way trade in health, personal care products and workplace chemicals. There are opportunities to better align our regulatory requirements to reduce unnecessarily duplicative activities and further leverage each other's regulatory capacities and scientific expertise, and to improve efficiencies and timeliness of product regulatory assessments.

#### **Joint Action Plan Initiatives**

- Implement a Common Electronic Submission Gateway to allow industry applicants the ability to submit large electronic documents related to pharmaceutical products simultaneously to the U.S. Food and Drug Administration and Health Canada and further catalyze increased review and collaboration on these products between the two regulatory agencies.
- Develop and adopt **common monographs** (e.g., including properties, claims indications, and condition of use) for routine over-the-counter drugs.
- Enhance collaboration on enforcement and compliance by increasing mutual reliance on each other's
  routine surveillance good manufacturing practices (GMP) inspection reports of manufacturing
  facilities for drugs and personal products, rather than having to conduct unnecessarily duplicative
  inspections in the other country.
- Align and synchronize implementation of common classification and labelling requirements for workplace hazardous chemicals within the mandate of the U.S. Occupational Safety and Health Administration (OSHA) and Health Canada.

#### What are the benefits?

Increased collaboration between regulatory agencies in the United States and Canada will reduce unnecessary duplicative costs for manufacturers of pharmaceutical and therapeutic products, further streamline regulatory decisionmaking, and minimize the delays in bringing health and personal care products to the marketplace, thereby expanding consumer choice without compromising the safety, efficacy, and quality of products.

Aligning and synchronizing the implementation of the Globally Harmonized System of Classification and Labeling of Chemicals for workplace chemicals to facilitate trade through reduced compliance costs associated with trans-border shipments of products and support both countries' competitiveness. It will also reduce the potential for confusion among systems and lead to benefits from increased worker protection and safety.

# **Environment**

Air pollution and climate change are challenges that know no boundaries. Given our shared environmental space and integrated economies, both countries are committed to deepening their long history of joint collaboration though regulatory approaches that will benefit the environment, industry and consumers.

# What is the opportunity?

The United States and Canada have a long tradition in jointly addressing air emissions, best exemplified by the 1991 United States–Canada Air Quality Agreement, which originally focused on the issue of acid rain. Since this time, both countries have made great strides in the ongoing effort to reduce harmful air pollution and prevent serious health challenges for its citizens. There are significant health and environmental benefits to expanding the Agreement, with a focus on reducing particulate matter.

In addressing climate change, both the United States and Canada have implemented aggressive emissions targets in the transportation sector. Continuing progressive and aligned action to reduce greenhouse gases from vehicles is a priority for both countries. There is an opportunity for regulators to work more closely with the aim of better synchronizing implementation of regulations and leveraging existing expertise.

# **Joint Action Plan Initiatives**

- Refine and enhance the existing Air Quality Committee (under the United States–Canada Air
  Quality Agreement) work plan with regard to information sharing, technical work-sharing, scientific
  collaboration and testing related to completed emission regulations for light-duty vehicles,
  which have been bilaterally coordinated.
- Work together to reduce greenhouse gas emissions from locomotives, building on the already
  extensive collaboration and coordination between both governments on locomotive air pollutant
  regulations.
- Environment Canada, U.S. Department of State, and the Environmental Protection Agency to consider
  an expansion of the United States-Canada Air Quality Agreement to address particulate matter,
  the air pollutant most commonly associated with premature mortality, based on comparable regulatory
  regimes in the two countries.

# What are the benefits?

Enhanced collaboration between the United States and Canada on vehicle emissions will leverage preexisting expertise among government regulators, provide regulatory certainty for industry through better synchronized timelines, attain environmental benefits through lower air emissions, and achieve cost savings through reduced fuel consumption. Enhanced collaboration on particulate matter would also ensure that both countries are taking the most effective actions to address this issue in a way that improves air quality and, hence, public health, to the benefit of all citizens in the United States and Canada.

# **Cross-Sectoral Issues**

Federal regulation is one of the basic tools of governments used to implement public policy, with each country following well-defined regulatory policies or rule-making procedures. Closer coordination on a number of cross-sectoral regulatory issues will complement the sectoral issues considered in this initial Joint Action Plan.

Ensuring that regulators consider the particular needs of small business is a priority for both countries.

# A. Small Business Lens

# What is the opportunity?

Both countries are looking to reduce regulatory burden on small businesses by developing tools and provisions that better integrate small business considerations in the design of regulations. United States–Canada collaboration can increase sensitivity and responsiveness to the needs of small businesses, particularly those engaged in cross-border trade.

### **Joint Action Plan Initiatives**

• Share approaches and tools being developed by the United States and Canada to assess and account for the **needs of small businesses** when developing regulations.

# What are the benefits?

Early information sharing will help inform implementation of Canada's Small Business Lens, announced in the 2011 Canadian federal budget, and implementation of the 2011 U.S. Presidential Memorandum to regulatory agencies on Regulatory Flexibility, Small Business and Job Creation.

# **B. Regulatory Approach to Nanomaterials**

# What is the opportunity?

Nanotechnology is a rapidly emerging field which deals with very small matter (one nanometre is one billionth of a metre). Nanomaterials are already used in a range of products—from tennis balls to paint—and are expected to be used increasingly to address a wide range of issues, such as more effective drug delivery, preservation of food and improved environmental decontamination. Both the United States and Canada are in the process of developing approaches to inform government oversight and strengthen regulation where necessary of nanotechnology applications. Early cooperation between both governments on regulatory aspects of nanomaterials will help ensure maximum alignment.

# **Joint Action Plan Initiative**

 Share information, and develop joint approaches, on regulatory aspects of nanomaterials—including terminology and nomenclature, as well as risk assessment and management.

#### What are the benefits?

Ensuring that the United States and Canada share information regarding each other's respective regulatory approaches to nanomaterials at an early stage will be critical in reducing risks to environmental and human health while fostering innovation. Additionally, considering a joint framework to align regulatory approaches will ensure consistency for consumers and industry within and between both countries.

# **Moving Forward**

The United States and Canada will implement the initial Joint Action Plan through bilateral regulatory-agency working groups, which, in cases where actions are currently being addressed under an existing bilateral Agreement or forum, will comprise the members of such Agreement or forum. Similarly, workplans, timelines, and deliverables will be developed and implemented under those Agreements and forums. Initiatives outlined in the initial Joint Action Plan will be carried out by lead departments and relevant agencies in the United States and Canada.

# **Working Groups**

Working groups, either already established or to be established, will assist in implementing all RCC initial Joint Action Plan items. Led by senior officials from the primary regulatory departments (United States and Canada) with representatives from other relevant agencies or groups, they will develop workplans and timelines, and will focus on achieving tangible and practicable deliverables throughout the duration of their work.

Stakeholder engagement will occur in a broad context, in part by seeking input from sectoral stakeholders during select RCC meetings. Working groups will be responsible for ensuring appropriate and adequate stakeholder engagement on issues within their purview. In addition, the normal consultative process will be used should any regulation or rule-making occur.

In developing solutions, working groups will be expected to identify mechanisms not only to alleviate current issues but also to foster ongoing alignment and prevent future unnecessary differences from occurring.

Working groups will provide periodic updates on their progress.

# **RCC Activities**

Meetings of the RCC will be held quarterly to review and discuss progress of the working groups. Stakeholder engagement sessions will be held as part of these meetings twice per year, and results of the RCC work will be made public on a regular basis.

The RCC will provide a midterm report on progress to leaders on these initiatives.

The RCC will closely monitor the working groups and will undertake to resolve systemic or horizontal challenges facing the working groups.

The RCC welcomes input from citizens on areas of further work to supplement the ideas that have already been forwarded.

The United States and Canada have an opportunity to take advantage of more integrated economies, i.e., trade relations and greater reliance on each others' regulatory outcomes. With common target outcomes it should not be necessary to do everything twice. Most importantly, this initial Joint Action Plan will provide working examples upon which new approaches can be developed on a broader range of sectors and initiatives in the future. Together, we can work towards a better aligned regulatory system that benefits citizens and businesses on both sides of the border.

This initial Joint Action Plan is not the end of the journey, but represents an important step along the path to enhanced regulatory cooperation between the United States and Canada.

