# UNITED STATES – CANADA REGULATORY COOPERATION COUNCIL

S

## JOINT FORWARD PLAN

AUGUST 2014



# TABLE OF CONTENTS

I	INTRO	DUCTION1		
II	INITIA	L J(	DINT ACTION PLAN	. 4
		RE	САР	. 5
		GEI	NERAL LESSONS LEARNED	. 8
III	FORWARD PLAN11			
		А	DEPARTMENT-LEVEL REGULATORY PARTNERSHIPS	14
		В	DEPARTMENT-TO-DEPARTMENT COMMITMENTS	15
		С	CROSS-CUTTING ISSUES	27
IV	NEXT	STE	PS	28
ANNEX: ASSESSMENTS OF EACH OF THE 29 INITIAL JOINT ACTION PLAN INITIATIVES				
		А	AGRICULTURE AND FOOD	31
		В	TRANSPORTATION	35
		С	HEALTH AND PERSONAL CARE PRODUCTS AND WORKPLACE CHEMICALS	38
		D	ENVIRONMENT	40
		Е	CROSS-SECTORAL AREAS	41

# I INTRODUCTION

In February 2011, President Obama and Prime Minister Harper launched the Canada-United States Regulatory Cooperation Council (RCC). The Leaders created the RCC to facilitate closer cooperation between our two countries to develop smarter and more effective approaches to regulation to make the United States (U.S.) and Canadian economies stronger and more competitive, while meeting the fundamental responsibilities to protect the safety and welfare of our citizens. They recognized that regulatory differences and duplicative procedures impose unnecessary requirements and costs on our citizens, businesses and economies.

The initial RCC Joint Action Plan – comprised of 29 initiatives – was launched in December 2011 to foster new approaches to regulatory cooperation and serve as a template for future efforts between Canada and the U.S. The initial *Joint Action Plan* provided an opportunity to enhance Canada-U.S. regulatory cooperation through the identification of specific regulatory issues and challenges that agencies on both sides of the border would work together to resolve or improve; using a variety of tools, such as enhanced technical collaboration, joint development and recognition of standards, work-sharing and lasting solutions to avoid future misalignments from developing.

These 29 initiatives covered a wide range of regulatory work, from transportation and agriculture to emerging areas such as developing a consistent approach to the regulation of nanomaterials. The initial *Joint Action Plan* has demonstrated the feasibility of deeper and more ambitious cooperation and the effort has delivered a number of important, specific results such as:

- **Common Electronic Submission Gateway**: This allows industry to submit electronic applications to both Health Canada and the U.S. Food and Drug Administration for pharmaceutical and biological products.
- Regulatory Oversight Regime on the Great Lakes & St. Lawrence Seaway: Transport Canada and the U.S. Coast Guard completed a Port State Control pilot project that involved 10 joint ship inspections to test the feasibility and benefits of mutual recognition of examinations, joint inspections, and sharing of inspection results.

- Zoning for Foreign Animal Diseases: The U.S. Department of Agriculture and the Canadian Food Inspection Agency have adopted an arrangement for the mutual recognition of animal disease zoning decisions. Guidance for implementing the arrangement, including agreed-upon processes and conditions for zoning recognition, has been developed.
- **Crop Protection Products:** Canada's Pest Management Regulatory Agency and the U.S. Environmental Protection Agency worked on aligning product reviews and risk assessment methodologies, including the development of a joint review process for pesticides with minor uses, which will reduce administrative burden on industry and provide simultaneous product access to growers.

The RCC also considered these initial 29 initiatives as a "laboratory" of sorts, with agencies employing various methods and approaches for strengthening our cooperation efforts, while identifying elements that would form the basis for a more long-term, systemic approach to regulatory cooperation between our countries. Over the last two years, the RCC and departments/agencies have learned a lot about what it takes to achieve more systematic regulatory cooperation. Our next phase of work will seek to make regulatory cooperation a routine, ingrained practice between Canadian and U.S. regulatory authorities.

In this RCC *Joint Forward Plan*, we will discuss what we have accomplished with the initial 29 initiatives as well as reflect on lessons learned by regulators and stakeholders who have worked on this effort. We will also present an approach to deepen and broaden our regulatory cooperation partnership moving forward.

# II INITIAL JOINT ACTION PLAN

### RECAP

The establishment of the RCC and issuance of the initial *Joint Action Plan* were important first steps in strengthening bilateral regulatory cooperation between the U.S. and Canada. Both countries have highly effective regulatory systems that achieve similar levels of protection and outcomes, and are based on generally compatible regulatory philosophies, institutions, and administrative practices.

These systems have developed and evolved independently over decades, and both are highly successful. But because we often have different or duplicative approaches to targeting the same outcomes, unnecessary and duplicative requirements have developed. The RCC is an effort to bring the systems into closer alignment.

Before the RCC was launched, a good and necessary foundation for cooperation was already in place. Importantly, both countries are committed to "good regulatory practices" (GRPs), including regulatory transparency, public participation in rulemaking, science-based decision making, data quality standards, and rigorous regulatory impact analysis. The use of GRPs in both countries helps regulators deliver smarter, more effective regulation that enhances economic competitiveness while maintaining high standards of public health, safety, and environmental protections.

In addition, Canada and the United States benefit from already well-established working relationships between many U.S. and Canadian agencies, and the presence of professional, expert regulators across the same fields of regulatory business.

The initial Joint Action Plan presented an opportunity for:

- unprecedented simultaneous dialogue among regulators about ongoing cooperation across multiple disciplines;
- an opportunity to consider how to remove or reduce unnecessary differences and unnecessary or duplicative requirements across a range of areas;
- practical experience in implementing a diverse set of initiatives, with specific work plans and deliverables;
- greater understanding of systemic changes required to move away from an individual rule-by-rule approach to a more holistic approach to our bilateral cooperation; and
- better understanding of cross-cutting challenges to regulatory cooperation that arise regardless of sector (e.g., information sharing constraints, fund sharing challenges, regulatory process differences).

With this in mind, Canada and the United States agreed to undertake work in several key representative sectors that involved departments and agencies with responsibilities for agriculture and food, transportation, health and personal care products, workplace chemicals, and the environment. We then worked to provide opportunities for federal regulators with complementary mandates to develop and implement detailed and ambitious "work plans." Each of the 29 Work Plans included timelines for work to take place and identified specific deliverables that were achievable within about two years. These work plans also provided opportunities for stakeholder engagement.<sup>1</sup>

What also animated these work plans was our shared belief that robust regulatory cooperation should give regulators the flexibility to use a wide range of tools to reduce unnecessary differences in regulation. We believe that regulatory cooperation can only be successful if it helps agencies advance their central policy missions and achieves smarter regulatory outcomes more efficiently. Collaborating on research, conducting

<sup>1</sup> RCC Work Plans can be found at: http://actionplan.gc.ca/page/rcc-ccr/initiatives-and-working-groups and http://www.trade.gov/rcc/

CANADA-UNITED STATES Regulatory Cooperation Council

joint pilot programs, and exploring work share opportunities can support core objectives of protecting human health, safety, and the environment by relying on the resources and expertise of trusted partners.

These principles were reflected in the RCC work plans, which encompassed a broad scope of cooperation activities. A recent <u>OECD case study</u><sup>2</sup> of the RCC summarized these various activities.

Since the public release of the 29 work plans, agencies and stakeholders have dedicated significant resources and attention to implementing those plans. In many cases, the initial *Joint Action Plan* represented work above and beyond the pre-existing priorities and regulatory agendas of the departments and agencies.

The RCC is proud of the hard work and progress made by the regulators who implemented the *Joint Action Plan*. This effort has provided tangible, specific results, including single window applications for stakeholders, inspection pilots, joint product reviews and simultaneous approvals, common standards, joint guidance, and alignment of regulations. It has also provided a number of general lessons that will inform our work going forward. We provide those general lessons below and an assessment of each of the 29 initiatives in the Annex.

<sup>2</sup> International Regulatory Co-operation: Case Studies, Vol. 2: The Canada-U.S. Regulatory Cooperation Council. http://www.oecd.org/gov/regulatory-policy/canada-usregulatorycooperationcouncil.htm

### **GENERAL LESSONS LEARNED**

Through work on each of the 29 initiatives, we have learned lessons about what makes international cooperation effective. Based on that work, as well as from meetings and conversations with stakeholders, agencies and policy officials, we have identified a number of general lessons that cut across this work. Please note that the following summary is not exhaustive, that some items may not be relevant for all agencies and/or initiatives, and that they are in no particular order.

### **BILATERAL DEPARTMENTAL COOPERATION, COORDINATION AND PLANNING**

- An issue-based Action Plan was a good place to start in addressing unnecessary regulatory differences and ascertaining what will be needed to better cooperate in the future.
- The RCC generated a dialogue on deeper cooperation simultaneously across multiple regulatory departments and contributed to a better understanding of what would be required for more systemic cooperation.
- Relationships matter for successful international regulatory cooperation, and open communication between colleagues helps establish a trust and rapport that is essential for implementing specific initiatives. In some cases, the RCC offered the first opportunity for regulators to work together; in other cases, the RCC provided a platform to renew or expand upon existing work.
- Regulators must lead the way to create and sustain change; they are the ones doing the work.

### SCOPE OF REGULATORY COOPERATION GOING FORWARD

- Regulatory cooperation does not encompass all regulatory activities within agencies. The RCC is focused on areas where benefits can be realized by regulated parties, consumers, and/or regulators without sacrificing outcomes such as protecting public health, safety and the environment. The identification of these priorities needs to be the product of careful consideration.
- Simply publishing a similar regulation may not necessarily be sufficient for reducing unnecessary differences because the various requirements associated with implementation can still result in duplicative and unnecessary costs for industries and consumers. Consistent approaches to regulatory implementation and compliance are important as well (e.g., testing, certification, inspection, guidance, etc.).
- Collaboration may also be valuable throughout our respective regulatory processes including during the early stages of the development of regulations.
- Regulatory divergences are not necessarily due to different regulatory objectives, and additional planning, coordination, and communication at all stages of rulemaking, including development and implementation, can help avoid unnecessary differences.
- Reliance and agreement on good regulatory practices (GRPs) is an essential foundation for successful regulatory cooperation. Regulatory cooperation encompasses a broad range of tools that may help prevent unnecessary differences in regulation, as well as allow agencies to use their limited resources more efficiently.

### **STAKEHOLDERS**

Stakeholders have a critical role to play in identifying unnecessary differences that create costs and challenges, as well as in suggesting opportunities for new initiatives. Meaningful and consistent opportunities for stakeholder engagement are important to success.

Transparency around the various RCC activities, including status of work plans, stakeholder engagement opportunities, and public events is very important. A broad perspective on all of the work being done by both governments increases public awareness.

### **GOVERNMENT-TO GOVERNMENT-LEVEL CONSIDERATIONS**

The experience of implementing the initial *Joint Action Plan* has also exposed some crosscutting issues to facilitating greater cooperation, which are common to many agencies (e.g., information sharing, joint funding).

Successful regulatory cooperation can generate benefits for regulated parties, consumers, and the regulators themselves. Consideration of these various benefits will support the identification of priorities for bilateral regulatory cooperation efforts.

High-level commitment to, and support of, the RCC provides needed strategic direction to advance regulatory cooperation.

# III FORWARD PLAN

Building on the initial *Joint Action Plan*, the momentum it has generated within government and with stakeholders, and the lessons learned over the last few years, the *Joint Forward Plan* represents a pivot point for the regulatory relationship between Canada and the U.S. Where appropriate, we will advance from the initial issue-based *Joint Action Plan* to new partnership arrangements and a framework of more institutionalized commitments by U.S. and Canadian regulators. The long-term goal is to have bilateral regulatory cooperation within the regular planning and operational activities of regulatory agencies.

To help guide this transition, and for the foreseeable future, the RCC will continue to provide central oversight and remain focused on government-to-government coordination, and intends to function as it has to date.

In the fall of 2013, we published notices in the *Canada Gazette* and U.S. *Federal Register* seeking public comment on how best to advance U.S.-Canada regulatory cooperation. We received a significant response, with thoughtful submissions from about 160 individuals and organizations, representing a wide range of sectors and regions. A number of themes emerged from the submissions:

- strong interest in advancing bilateral regulatory cooperation work between Canada and the United States;
- desire for more regular opportunities for stakeholder consultation and input, both in identifying regulatory cooperation priorities and in their implementation;
- interest in deepening the work in regulated areas that were included in the initial Action Plan, as well as expanding into new areas (e.g., energy efficiency); and
- recognition of the importance of "institutionalizing" regulatory cooperation between the regulators so that working in partnership becomes an ongoing, routine part of how U.S. and Canadian regulators operate.

Based on this stakeholder input, what we have learned through implementation of the initial 29 initiatives, and discussions between the RCC and agencies on both sides of the border, this *Joint Forward Plan* outlines three key components of our future work:

- (A) <u>Department-Level Regulatory Partnerships</u>: Public documents that will outline RCC strategies and the framework for how the activities will be managed between regulatory partners.
- (B) <u>Department-to-Department Commitments and Work Plans</u>: A first set of commitments to cooperate in specific areas of regulatory activity, for which technical work plans will be developed annually
- (C) <u>Cross-Cutting Issues</u>: Identifying current laws, policies and practices in both governments that can present challenges/opportunities to international regulatory cooperation, regardless of sector, and considering new tools and approaches to support regulators in achieving their cooperation objectives where possible.

### **A DEPARTMENT-LEVEL REGULATORY PARTNERSHIPS**

In order to improve new bilateral regulatory cooperation processes between Canadian and U.S. regulators, where appropriate, agencies will work together to implement the elements necessary to enable them to work in partnership. As a first step, over the next six months regulators will develop Regulatory Partnership Statements (RPSs). These statements will be public documents that outline the framework for how cooperative activities will be managed between agencies.

Given the need for flexibility, the exact form of these arrangements will vary from agency to agency. In some cases, agencies have vehicles for cooperation already in place, and in other cases enhancements or entirely new frameworks will need to be established. The RPSs are intended to outline the bilateral regulatory partnership arrangements.

Although the structure and format of the RPSs will vary by partnership, they should all include three key elements critical to effective cooperation:

- *High-level governance between the agencies and a commitment to work together moving forward.*
- Opportunities for stakeholders to provide input, to inform strategies, identify priorities and discuss progress on the implementation of initiatives as appropriate.
- A mechanism for annual reviews of work plans to consider adjustments and provide status updates on the progress.

Each of these Regulatory Partnership Statements will be posted on the RCC websites at <u>www.trade.gov/rcc</u> and <u>http://actionplan.gc.ca/rcc</u>.

### **B DEPARTMENT-TO-DEPARTMENT COMMITMENTS**

The Regulatory Partnership Statements (RPSs) will outline the structure for ongoing agency to agency work moving forward. While those RPSs are being developed, we want to build on momentum to date and begin or continue work in a variety of areas.

Below we provide a number of commitments that U.S. and Canadian departments/ agencies have worked together to develop. These commitments have been informed by various sources and experiences, including: (1) input received from stakeholders via the Fall 2013 *Canada Gazette* and U.S. *Federal Register* consultation period described above, (2) the expertise and experience of regulatory departments based on efforts to date, and (3) initiatives within the initial group of 29 work plans that should continue or be refined to reflect ongoing additional work.

We believe the scope of work between the regulatory agencies and authorities listed below will benefit Canadian and U.S. stakeholders, while improving the efficiency and effectiveness of the regulatory systems in both countries.

The commitments below identify objectives for bilateral cooperation over a three to five year period in specific areas of regulatory activity. These commitments will be followed in six months with more detailed work plans that will coincide with the public release of the RPSs. The commitments are not intended to be inclusive of all regulatory activity to be undertaken in a given area by either government. Cooperative work will be focused where tangible benefits and improved outcomes can be achieved by working in partnership. These benefits provide useful criteria for regulators to consider when identifying priorities for joint work; assessing whether working together will (in no particular order):

- benefit regulated parties, for example by eliminating a duplicative requirement and generating savings in time or cost;
- benefit consumers, for example by lowering prices and through simultaneous product availability in both countries, or by creating efficiencies that improve protections;

• benefit regulators, for example through greater efficiency and effectiveness by avoiding duplicative effort and enabling joint approaches to common risks.

The commitments that follow should be considered in this context. Decisions on what work to undertake in a cooperative or partnership context will be the subject of discussion and planning at a senior level between partner departments as appropriate.

It should be noted that the following commitments do not capture all regulatory cooperation efforts between Canada and the United States. For example, independent or arms-length U.S. and Canadian agencies also engage in cooperative activities with their respective counterparts. This is a separate category of cooperative work that supports the goals of the RCC but which involves activities and outcomes that occur outside of the RCC process and are not RCC commitments. This independent work includes, for example, ongoing efforts between Health Canada and the U.S. Consumer Product Safety Commission to align their position on toy safety work within the American Society for Testing and Materials (ASTM) Toy Safety Subcommittee in furtherance of consumer product safety.

Additional commitments, as well as updates and revisions to them, will be made in the course of regular planning between the relevant Canadian and U.S. agencies, reflecting changing circumstances and the emergence of new opportunities.

Nothing in this *Joint Forward Plan* is intended to give rise to rights or obligations under domestic or international law.

### **U.S. DEPARTMENT OF AGRICULTURE / CANADIAN FOOD INSPECTION AGENCY**

*Meat inspection and certification*: In the area of meat inspection and certification, the Canadian Food Inspection Agency (CFIA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) will work together and, where feasible, make routine changes and updates to their slaughter and processed meat inspection policies and procedures in an effort to achieve closer alignment between inspection system requirements and eliminate unnecessary or duplicative requirements. CFIA and FSIS will work together to identify areas of mutual interest and collaboration based on the best available science and technological advances in our respective meat inspection systems and modernization approaches. This work will also enable CFIA and FSIS to further streamline the efficient export and import of meat through electronic certification processes.

*Plant health*: The Canadian Food Inspection Agency and U.S. Department of Agriculture's Animal and Plant Health Inspection Service will continue to advance a perimeter approach to facilitating safe bilateral trade and protecting Canada and the United States from risks posed by plants and plant products arriving from third countries. This will include aligned phytosanitary import requirements and related systems wherever possible with a view to utilizing information from phytosanitary inspections conducted by one country to inform decisions by the other country, and working towards reducing certification and inspection requirements between the two countries.

Animal health: In order to expedite and simplify trade, the Canadian Food Inspection Agency and U.S. Department of Agriculture's Animal and Plant Health Inspection Service will work together to develop and implement their respective electronic certification and delivery systems, and collaborate on animal health requirements and assessments for the movement of animals and animal products. Collaborative work will continue on Foreign Animal Disease Zoning, joint site visits to third-countries where there are animal health risks of common concern, and related data collection and approaches to risk mitigation. This will result in a more stable and predictable trading environment for Canadian and U.S. stakeholders.

## U.S. COAST GUARD (DEPARTMENT OF HOMELAND SECURITY) AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY / TRANSPORT CANADA

*Marine Safety and Security*: Transport Canada the U.S. Coast Guard and the U.S. Environmental Protection Agency will work together to coordinate as appropriate their marine safety, environmental stewardship, and security regulatory systems, focusing on both regulations and implementation procedures for vessels in coastal waters. Initial consideration will be given to regulations, implementing procedures or practices that pertain to training and certification of seafarers, inspection of foreign vessels, ballast water inspection, and minimum crew complement for Coastal shipping in the Arctic, East and West coasts, and the Great Lakes. The agencies will continue to collaborate to identify mutually acceptable mechanisms (or practices) that recognize any existing overlap in each agency's enforcement and inspection regimes, with the goal of minimizing the number of duplicative inspections conducted on vessels operating on the Great Lakes and St. Lawrence Seaway while maintaining the same level of safety, security, and environmental protection.

#### **U.S. DEPARTMENT OF ENERGY / NATURAL RESOURCES CANADA**

*Energy Efficiency Standards:* Natural Resources Canada and the U.S. Department of Energy have established the goal of aligning new and updated energy efficiency standards and test methods for energy-using equipment through enhanced information sharing and their cooperative development and implementation, to the extent practicable and permitted by law. This includes a commitment to: annually share work plans (schedules) for test procedures and standards; develop guidelines for frequency of interaction and information sharing (e.g., test data, market analyses, etc.); mutually participate in the process to establish standards and testing requirements; and leverage multilateral initiatives to advance energy efficiency objectives. *Natural Gas Transportation Standards*: In the area of alternative fuel use in transportation, namely natural gas, Natural Resources Canada and the U.S. Department of Energy will continue to build on previous work and facilitate the development of common codes and standards by industry organizations, and explore any opportunities for alignment among stakeholders. This includes a commitment to share information, identify emerging areas in natural gas deployment, and explore challenges in codes and standards harmonization.

### **U.S. ENVIRONMENTAL PROTECTION AGENCY / TRANSPORT CANADA**

*Locomotive Emissions:* Transport Canada (TC) and the U.S. Environmental Protection Agency (EPA) will build on the already extensive collaboration and coordination between both governments to improve the alignment of greenhouse gas protocols and air pollutant regulations for locomotives including coordination of regulatory agendas, joint work to develop new requirements, and the sharing of research and compliance data and information. More specifically, TC and the EPA will work with key stakeholders to finalize a Canada-U.S. Voluntary Action Plan to Reduce Greenhouse Gas Emissions from Locomotives. This will provide a framework for working together into the future and include regular reporting on progress.

### **U.S. ENVIRONMENTAL PROTECTION AGENCY / ENVIRONMENT CANADA**

*Vehicle and engine emissions:* Environment Canada and the U.S. Environmental Protection Agency will continue collaborating under the U.S.-Canada Air Quality Committee (AQC) towards the development of aligned vehicle and engine emission regulations and their coordinated implementation. Consistent with these objectives, these cooperative efforts are expected to include information-sharing, technical work-sharing, scientific collaboration and testing related to vehicle and engine emissions. For this work the related planning, reporting and stakeholder engagement functions will continue to occur through the AQC process.

## U.S. ENVIRONMENTAL PROTECTION AGENCY / ENVIRONMENT CANADA & HEALTH CANADA

*Chemicals Management:* Environment Canada, Health Canada and the U.S. Environmental Protection Agency will collaborate in efforts to align chemical regulatory processes, specifically through the development of common approaches to address emerging risk issues and jointly considering how the use of novel data can inform the assessment of chemicals. Further, they will collaborate in efforts to develop common approaches for regulatory reporting requirements for new uses of chemical substances (Significant New Activity provisions/Significant New Use Rules).

#### **U.S. ENVIRONMENTAL PROTECTION AGENCY / PEST MANAGEMENT REGULATORY AGENCY**

*Crop protection products*: Health Canada's Pest Management Regulatory Agency and the U.S. Environmental Protection Agency's Office of Pesticide Programs will enhance the existing bilateral system of joint product reviews, including for use expansion submissions, and move towards the establishment of a single application for crop protection products that will be accepted in both countries. This will include coordinated work planning; data sharing; aligning approaches to risk assessment; coordination of submissions; and the alignment of submission requirements. In addition, the Agencies will jointly develop information technology solutions for applicants to facilitate the joint review and processing of pest control product applications submitted to both countries.

### **U.S. FOOD AND DRUG ADMINISTRATION / CANADIAN FOOD INSPECTION AGENCY**

*Food safety:* The Canadian Food Inspection Agency (CFIA), Health Canada and U.S. Food and Drug Administration (FDA) will finalize the assessment of each other's food safety systems (excluding meat, poultry and eggs products) and establish a food safety systems recognition arrangement based on the results. The exchange of food safety information will be increased to help both countries make informed risk-based regulatory decisions. As the FDA and the CFIA implement their modernized food safety rules and regulations, they will work together to ensure that their systems deliver comparable public health outcomes and reduce unnecessary duplication wherever possible.

### **U.S. FOOD AND DRUG ADMINISTRATION / HEALTH CANADA**

*Pharmaceutical and Biological Products*: Health Canada and U.S. Food and Drug Administration will continue to work closely together to harmonize and align their pre and post-marketing surveillance requirements and standards (including pharmacovigilance issues) through the work of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, the International Pharmaceutical Regulators Forum and the International Coalition of Medicines Regulatory Authorities. Regulators will continue to share inspection schedules bilaterally and through the Pharmaceutical Inspection Co-operation Scheme and to promote leveraging of inspection resources to maximize inspection coverage. Regulators will also continue to expand the Common Electronic Submission Gateway for the biological and pharmaceutical industry, where appropriate.

*Over-the-Counter Products*: Health Canada and U.S. Food and Drug Administration will coordinate and adjust their respective Over-the-Counter (OTC) monographs development processes for OTC drugs to reduce the regulatory burden on stakeholders.

*Medical Devices*: Health Canada and U.S. Food and Drug Administration will continue to work closely together on pre and post market regulatory convergence topics, including in particular, through the International Medical Devices Regulators Forum (IMDRF). IMDRF aims to accelerate international medical device regulatory harmonization and convergence for regulators and stakeholders worldwide.

*Veterinary Drugs*: Health Canada and U.S. Food and Drug Administration will coordinate their respective veterinary drug marketing application submission and review processes to enable simultaneous product reviews. They will coordinate standards development as appropriate, as well as assessment activities pertaining to the pre-market evaluation of veterinary drugs. Further work in this area will also explore the availability of electronic templates that could be used to submit veterinary drug applications.

## OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (U.S. DEPARTMENT OF LABOR) / HEALTH CANADA

*Workplace chemicals*: Health Canada and the U.S. Department of Labor will work together to coordinate the adoption of future updates of the Globally Harmonized System for Classification and Labelling of Workplace Chemicals (GHS) to facilitate common approaches and synchronized implementation in Canada and the United States This includes developing a mechanism to maintain alignment as the system is updated and modernized or new requirements or standards are put in place, exploring innovative methods to jointly engage stakeholders as well as enhanced collaboration on common interpretation and guidance materials.

### NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION (U.S. DEPARTMENT OF COMMERCE) / DEPARTMENT OF FISHERIES AND OCEANS

*Aquaculture:* The Department of Fisheries and Oceans (DFO) and the National Oceanic and Atmospheric Administration (NOAA) will undertake greater cooperation in environmental management of the aquaculture sector and identify potential areas for regulatory alignment. Building on the existing bilateral relationship and expertise in both countries, DFO and NOAA will explore initiatives that yield mutual benefits, such as information and data sharing on overall environmental management of the aquaculture sector, aquaculture siting decisions, area management approaches and environmental monitoring and assessment tools. NOAA and DFO are the lead agencies for this initiative and will work with relevant departments and agencies in both countries as required.

### **U.S. DEPARTMENT OF TRANSPORTATION / TRANSPORT CANADA**

*Connected Vehicles*: Transport Canada and the U.S. Department of Transportation will coordinate and collaborate on Vehicle to Vehicle (V2V) and Vehicle to Infrastructure (V2I) communications technology and applications development and implementation for light- and heavy-duty vehicles, including architecture and standards to support interoperable deployment. This will include, where appropriate, joint planning and priority-setting, collaborative research projects, as well as information exchanges to support analyses as well as architecture and standards development.

## PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION (U.S. DEPARTMENT OF TRANSPORTATION) / TRANSPORT CANADA

*Transportation of Dangerous Goods*: Transport Canada and the U.S. Pipeline and Hazardous Materials Safety Administration will strive to more closely align their regulatory regimes for the transportation of dangerous goods, including working to align national standards and regulations; sharing data, analyses and research; and synchronizing consultations with industry when feasible. Objectives include: aligning Canadian and U.S. placarding requirements; mutual recognition of United Nations (UN) standard pressure receptacles (UN cylinders); recognition of inspection under U.S. requirements for highway; alignment and mutual recognition of tank truck (cargo tank) standards, including vehicles used to transport bulk explosives and repair facilities; mutual recognition of conditions for One Time Movement Approvals; and explosives approvals. Furthermore, both parties will undertake an examination of each jurisdiction's Special Permits and Approvals regimes to identify possible opportunities for further harmonization. Lastly, rulemaking cooperation guidelines will be jointly developed to promote cooperation and greater efficiencies in the early stages of the rulemaking process.

## NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION (U.S. DEPARTMENT OF TRANSPORTATION) / TRANSPORT CANADA

*Motor Vehicle Safety Standards*: Transport Canada (TC) and the National Highway Traffic Safety Administration (NHTSA) will work to align new and updated light- and heavyduty vehicle motor vehicle safety standards through new processes and protocols to facilitate joint work and partnership. This will be done through enhanced communication and insight on future safety needs to be addressed, coordination of standards development agendas, and collaboration at the earliest stages of the contemplation of new regulations by exchanging rulemaking priorities and identifying rulemaking initiatives of common interest. TC and NHTSA may undertake joint testing and research, joint and collaborative risk assessments, and exchange technical data and information to support future aligned standards development decisions in both countries. They will also consider how single test methodologies could be implemented in both countries. Initial regulatory alignment priorities will include side impact, ejection mitigation, and motorcycle brake systems.

## FEDERAL RAILROAD ADMINISTRATION (U.S. DEPARTMENT OF TRANSPORTATION) / TRANSPORT CANADA

*Rail Safety*: Recognizing the high degree of regulatory cooperation and alignment in this sector, Transport Canada and the Federal Railroad Administration will put the necessary processes and protocols in place to coordinate joint development of regulatory standards focused on existing and emerging railway safety issues such as train control systems and fatigue management, with a view to maintaining the alignment of the existing regulatory systems as they are modernized and new requirements emerge.

# FEDERAL AVIATION ADMINISTRATION (U.S. DEPARTMENT OF TRANSPORTATION) / TRANSPORT CANADA

*Aviation Regulations*: Transport Canada (TC) and the Federal Aviation Administration (FAA) will continue to collaborate in the area of aviation safety. They will establish procedures to: identify safety initiatives of common interest; exchange regulatory priorities; and develop opportunities for joint regulatory work. The two organizations will collaborate on safety concerns identified through Commercial Aviation Safety Team (CAST) meetings and other collaborative fora. TC and the FAA will also strengthen their relationship by enhancing communication and sharing data and documentation to align as much as possible their respective rulemaking programs.

## PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION (U.S. DEPARTMENT OF TRANSPORTATION) / NATURAL RESOURCES CANADA

*Explosives Classification:* Natural Resources Canada and the Pipeline and Hazardous Materials Safety Administration (U.S. Department of Transportation) will work to align and promote the safe management of explosive materials including classification requirements (Transportation of Dangerous Goods Class 1). This will include explosives classification approvals issued by either party and a process addressing issues affecting regulatory reciprocity. Efforts will be made to align test procedures in order to reduce discrepancies in explosives classification for producers and to align labelling information in order to ensure consistent outcomes in occupational health and safety.

### **U.S. CONSUMER PRODUCT SAFETY COMMISSION / HEALTH CANADA**

*Toy Safety:* During discussions connected with the U.S.-Canada Regulatory Cooperation Council, staff from the U.S. Consumer Product Safety Commission (CPSC)<sup>3</sup> and Health Canada (HC) reaffirmed their commitment to collaboration in the development of the strongest possible toy safety requirements. Staff from both agencies participate in the ASTM International Toy Safety Subcommittee (ASTM F-15.22), a standards development body of particular significance in North America. Most federal toy safety regulations enforced by the CPSC are, by law, derived from the ASTM consensus reference standard. In Canada, mandatory safety requirements for toys in the *Canada Consumer Product Safety Act* and its associated regulations are established using various standards, including those set by ASTM. The aim of CPSC-HC collaboration in the F-15.22 subcommittee is to maximize the potential for aligned positions at the highest possible level of safety between the two regulators as the ASTM standard is revised, thus increasing the likelihood of not only aligned approaches in the two jurisdictions, but also increased safety benefits for consumers.

<sup>3</sup> **Independent Track:** This commitment is distinct from the others listed above, and is an example of cooperative work led by an independent agency. It supports the goals of the RCC but whose activities and outcomes occur wholly outside of the RCC process, following the agencies' own missions and work plans.

### **C CROSS-CUTTING ISSUES**

In the course of implementing the initial RCC *Joint Action Plan*, it has become clear that certain laws and/or policies in both governments can present challenges to international regulatory cooperation, regardless of sector. These cross-cutting issues include areas such as: sharing information with foreign governments, joint funding of new initiatives and our respective rulemaking processes.

The RCC will explore certain cross-cutting issues in greater depth over the next year to get a better understanding of the existing laws and policies that govern the issues and identify the specific challenges and opportunities that these laws and policies present to enabling cooperation going forward.

# IV NEXT STEPS

### **THREE MONTHS:**

- The RCC will host a conference in Washington, DC geared towards stakeholders and federal regulators in both countries in order to launch discussions concerning the implementation of the *Joint Forward Plan*.
- As part of the 2014 North American Leaders Summit commitments, representatives from the Mexican Government will be invited to observe the government-togovernment and stakeholder sessions.

### **SIX MONTHS:**

- Regulatory Partnership Statements will be posted publicly.
- Technical work plans detailing the department-to-department commitments, and supporting the objectives outlined in the Regulatory Partnership Statements, will also be developed with the input of stakeholders.

### **12 MONTHS:**

- Both governments will explore horizontal issues in greater depth, particularly related to information sharing, funding cooperation, and regulatory process differences.

### **ONGOING:**

- The RCC will continue to provide public updates on the progress of implementation through regular RCC newsletters and website announcements.
- Technical work plans detailing department-to-department commitments will be reviewed and accordingly updated annually.
- Engagement between lead regulators and stakeholders will continue on a regular basis and be organized around department-to-department commitments.
- A RCC conference for stakeholders and regulators will be held annually.

# ANNEX: ASSESSMENTS OF EACH OF THE 29 INITIAL JOINT ACTION PLAN INITIATIVES

Both governments learned a lot while implementing the initial *Joint Action Plan*. The results from some work plans far exceeded expectations. Other work plans achieved less obvious, clear results, but served to identify barriers to cooperation that will help inform future work. If international regulatory cooperation were easy in every area, it would have been done a long time ago. A realistic assessment of the initiatives is essential to continue building on the significant progress to date.

### A AGRICULTURE AND FOOD

#### **FOOD SAFETY**

**Common Approaches to Food Safety**: The Canadian Food Inspection Agency, the U.S. Food and Drug Administration (FDA), Health Canada, and the Public Health Agency of Canada have completed assessments of the operations of the Canadian and U.S. food safety systems (not including meat, poultry and processed egg products) to determine if the systems provide comparable public health outcomes. The reports are being finalized and will inform the development of a Canada-FDA food safety systems recognition arrangement that will form a strong basis for enhanced regulatory cooperation between Canada and the United States such as the exchange of food safety information to help both countries make informed risk-based regulatory decisions. This will proceed as efforts continue in both countries to modernize food safety regulatory regimes.

**Equivalence of Meat Safety Systems**: The Canadian Food Inspection Agency (CFIA) and the U.S. Food Safety Inspection Service (FSIS) have completed a side-by-side comparison review and assessment of Canadian and U.S. meat safety standards. This exercise revealed the existence of some outdated requirements in both Canada and the U.S. that were subsequently updated. The exercise also served to highlight the difficulties inherent in comparing two highly technical regulatory systems. The CFIA and FSIS will continue to work together to ensure ongoing alignment and to maintain the equivalence of the two inspection systems.

**Meat and Poultry Product Export Certification**: An assessment of all certification requirements has been completed and some outdated requirements were updated. Work is underway to eliminate the veterinary signature requirement on export certificates for beef and pork. On an ongoing basis, The Canadian Food Inspection Agency and the U.S. Food Safety Inspection Service will work jointly to keep the requirements current and emphasis will be placed both on simplifying and automating the certification process.

**Mutual Reliance on Food Testing Results**: The Canadian Food Inspection Agency, Health Canada, and the U.S. Food and Drug Administration (FDA) have compared Canadian and U.S. accreditation criteria for food testing laboratories and analyzed the similarities between them. This analysis examined changes to food safety laboratory accreditation requirements that are possible as part of broader food safety legislation modernization efforts in both countries and which are expected to result in more aligned requirements between Canada and the United States. Moving forward, Canadian and U.S. food safety regulators will endeavor to jointly develop criteria, processes, and tools to facilitate mutual reliance on food testing results under the direction of an existing Canada-FDA Joint Committee on Food Safety.

#### AGRICULTURAL PRODUCTION

**Crop Protection Products:** This initiative further aligned product reviews and, as a result, maximum pesticide residue limits/tolerances. The work streamlined the processes for aligning domestic and import maximum residue limits for pesticides with minor uses. This approach will reduce administrative burden on industry and provide earlier access for growers. Crop groupings have been further harmonized to increase the number of minor uses and facilitate mutual reliance. Working with industry, certain data requirements and submissions processes were aligned to eliminate duplicative work for applicants. This included the development of the first shared review template for chemistry specifications.

**Veterinary Drugs:** The work to further align product approvals resulted in two simultaneous approvals and on-going work on five simultaneous review pilot projects involving the U.S. Food and Drug Administration, Health Canada and submission sponsors. Each pilot focuses on different aspects of the submission and review processes. The lessons learned through the execution of these pilot projects are being used to develop a standard Canada-U.S. simultaneous veterinary drug review process that submission sponsors will be able to use to seek simultaneous product review decisions in both countries. Further work in this area will include an ongoing mechanism for simultaneous product reviews and discussions on the availability of electronic templates which could be used to submit veterinary drug applications in the future.

**Perimeter Approach to Plant Protection**: Plant health authorities in Canada and the United States have developed a draft Memorandum of Understanding that establishes a framework for ongoing cooperation on plant health issues of mutual concern. In addition, two pilot projects were launched under this initiative, one to jointly manage chrysanthemum white rust and another to revise the Canada-U.S. greenhouse certification program; both of these are ongoing.

**Zoning for Foreign Animal Diseases**: Both governments have adopted an arrangement for the mutual recognition of animal disease zoning decisions. The arrangement formalizes the intent of each country to accept the other's decisions on establishing, maintaining and releasing a disease control and eradication zone. A guidance framework for implementing the arrangement, including agreed-upon processes and conditions for zoning recognition, has been released for stakeholder consultation. Once the guidance framework is adopted, processes will be in place to continue or rapidly reinstate trade in animals and animal products between disease-free areas within Canada and the United States, should a foreign animal disease outbreak occur.

#### MARKETING

**Meat Cut Nomenclature**: Canada and the United States have established a system to ensure harmonization of the terminology used for select wholesale cuts of meat. Many Canadian names for wholesale meat cuts can now be used interchangeably with their U.S. equivalents and vice versa. The new joint meat cut nomenclature system, known as the Institutional Meat Purchase Specifications (IMPS), is currently under consultation. Common use of meat cut terms benefits industry by simplifying trade and eliminating costs associated with maintaining separate inventories. **Financial Protection for Fresh Produce Sellers**: Over the course of the RCC, the United States and Canada have discussed how best to obtain comparable outcomes to the financial protection measures available to produce sellers in the United States and Canada. Canada has amended the *Safe Foods for Canadians Act* which provides authority for regulations which will require membership in a single, third-party dispute resolution body for fresh produce buyers and sellers who trade interprovincially or internationally. Once implemented, a single dispute resolution body approach may benefit fresh produce sellers operating in Canada by providing a single, unified set of rules governing instances of slow, partial, and/or no-pay. Additional options to further comparable outcomes for fresh produce and other stakeholders as part of Industry Canada's statutory review of insolvency legislation. The responsible departments and agencies of the United States and Canada will continue to engage on this issue outside of the RCC, using such fora as the U.S.-Canada Consultative Committee on Agriculture.

### **B TRANSPORTATION**

#### SURFACE (ROAD AND RAIL)

**Existing Motor Vehicle Safety Standards:** Transport Canada and the National Highway and Traffic Safety Administration aligned motor vehicle safety standards for tires (including winter tires) and for frontal impact occupant protection. The process for additional regulatory amendments is well underway, including those for lighting requirements, controls and displays, vehicle theft prevention and under-ride guards.

**New Motor Vehicle Safety Standards:** Transport Canada (TC) and the National Highway Traffic Safety Administration (NHTSA) completed several collaborative research projects together, including quiet vehicles and child restraints, and have initiated joint planning of future research and regulatory development work in other areas, including alternative-fuel vehicle safety and clean technologies such as low rolling resistance tires. TC and NHTSA are also in the process of updating their existing Memorandum of Cooperation to facilitate enhanced standards development collaboration. Finally, amendments were made to Canada's *Motor Vehicle Safety Act* to facilitate future alignment between the two countries.

**Rail Safety Standards:** Transport Canada and the Federal Railroad Administration have established a bilateral process for the development of rail safety requirements. They will sign a Memorandum of Cooperation to facilitate the exchange of information on rail-related safety research and regulatory actions.

**Intelligent Transportation Systems:** Transport Canada (TC) and the U.S. Department of Transportation (USDOT) established a mechanism for coordinating updates to their national Intelligent Transportation Systems (ITS) Architectures, including the Border Information Flow Architecture, to ensure that technology deployments in both countries adhere to the same manufacturing and operating standards, thereby reducing development and implementation costs. Ongoing alignment work on ITS is supported by two Memoranda of Cooperation signed in 2010. TC and the Federal Highway Administration (FHWA) jointly developed an implementation plan for the installation of Border Wait Time measurement systems at priority international border crossings and completed pilot projects at two bridge crossings in the Buffalo/Niagara Falls area, which will facilitate additional deployments on the Canada-U.S. border. TC and the USDOT worked with the American Association of State Highway and Transportation Officials (AASHTO) on the field infrastructure footprint analysis project which will help ensure coordinated deployment of Connected Vehicles technology. Earlier this year, NHTSA announced that it would begin taking steps to enable vehicle-to-vehicle (V2V) communication technology for light-duty vehicles, which could become a potential area of RCC focus moving forward.

#### MARINE

**Marine Transportation Security Regulations:** Transport Canada (TC) and the U.S. Coast Guard (USCG) have jointly developed Guidelines Respecting Marine Security Regulatory Development Collaboration to facilitate bi-lateral regulatory collaboration thereby ensuring ongoing regulatory alignment for policies, bulletins and regulations development. The two departments have developed joint regulatory priority lists and completed a comparative study of Canadian and U.S. regulations so that regulatory differences can be identified and prioritized for possible legislative amendments or other cooperation work. TC has proposed amendments to the *Marine Transportation Security Regulations* to align the definition of Certain Dangerous Cargoes between Canada and the United States and provide authority to allow TC to enter into Alternative Security Arrangements with the USCG.

**Regulatory Oversight Regime on the Great Lakes & St. Lawrence Seaway:** Transport Canada and U.S. Coast Guard completed a Port State Control pilot project that involved 10 joint ship inspections to test the feasibility and benefits of mutual recognition of examinations, joint inspections and sharing of inspection results. Lessons learned during the pilot project will lead to recommendations for a course of action that eliminates unnecessary duplication of inspections, screening and reporting regimes. The two departments are developing possible approaches for mutual recognition of regulatory oversight regimes to reduce the number of inspections conducted on lakers while maintaining the same level of safety.

**Life-Saving Appliances:** Draft, common life jacket standards have been co-developed by a bi-national industry consensus body, which includes both Transport Canada (TC) and the U.S. Coast Guard (USCG).. TC and the USCG have agreed to an implementation plan to synchronize amendments to their regulations to adopt the new standard once it is complete. A combined Canada/U.S. technical panel will ensure the ongoing alignment of the harmonized Standard. A TC-USCG Memorandum of Understanding has been drafted to set forth guidelines for cooperation concerning approval, testing and monitoring of the manufacture of wearable life jackets acceptable for use in both Canada and the United States.

**Construction/Safety Standards for Small Craft:** Transport Canada (TC) has developed Memoranda of Understanding with the American Boat and Yacht Council (ABYC) and the National Marine Manufacturers Association (NMMA) to move into closer alignment with the U.S. by incorporating ABYC standards and NMMA certification for boat construction. This will reduce duplication of work for both administrations and will reduce the burden on boat manufacturers. As well, TC and the U.S. Coast Guard are drafting a Memorandum of Understanding covering enhanced collaboration for ongoing alignment, compliance monitoring and recalls.

### **OTHER TRANSPORTATION ISSUES**

**Dangerous Goods Means of Containment**: Transport Canada and the U.S. Pipeline and Hazardous Materials Safety Administration are moving their transportation of dangerous goods regulations into closer alignment. Regulatory amendments were made to align new and revised standards pertaining to the selection, design and manufacture of means of containment used in the transportation of dangerous goods, mutual recognition of United Nations standard pressure receptacles, recognition of inspection under U.S. requirements for highway tanks and a closer alignment of placarding requirements. A Memorandum of Cooperation was also signed between United States and Canadian officials regarding the safe transportation of dangerous goods that solidifies international collaboration, information sharing, and policy and enforcement coordination.

**Unmanned Aircraft Systems:** Transport Canada (TC) and the Federal Aviation Administration (FAA) signed Rulemaking Cooperation Guidelines to promote cooperation in the early stages of the rulemaking process, which will help ensure alignment of Canadian and U.S. Unmanned Aircraft Systems (UAS) programs as both countries prepare to propose new UAS regulations. The FAA provided and discussed with TC the release of their UAS Roadmap and a Comprehensive Plan on the UAS Path Forward. TC and the FAA have coordinated on efforts to address the increase in illegal UAS operations.

# C HEALTH AND PERSONAL CARE PRODUCTS AND WORKPLACE CHEMICALS

**Common Electronic Submission Gateway:** The Common Electronic Submission Gateway (e-Gateway) was successfully implemented in January 2014. The e-Gateway allows industry to submit applications for the approval of pharmaceuticals and biological products to both Health Canada (HC) and the U.S. Food and Drug Administration (FDA). The ability to accept submissions securely over the Internet is new to Canada and represents a cost and time savings for industry, as well as a benefit to the regulator and potentially to Canadian consumers, who may enjoy access to new medicines more quickly as a result of the efficiency of electronic submissions. In the next phase of work, HC and the FDA will work together to expand the e-Gateway for the biologics and pharmaceutical industry.

#### **Over-the-Counter Therapeutic Products Approval and Licensing (Common**

**Monographs):** The work to develop and adopt common monograph elements for routine over-the-counter drugs has resulted in the identification of a monograph entitled "Antihistamines for the Common Cold." The completion of this project led to the identification of clear differences in monograph development processes. A key lesson from this work has been that aligning individual monographs may not deliver significant and timely benefits to regulators or industry; however, the frequent communication and excellent relationship between the members of the working group established a new pathway to exchange scientific data and allowed for the discussion of a variety of regulatory issues. As such, work in this area will focus on aligning the respective monograph development processes, thereby allowing for a reduction, when possible, in the regulatory burden for stakeholders.

**Good Manufacturing Practices**: Through this initiative, the U.S. Food and Drug Administration (FDA) and Health Canada (HC) have had the opportunity to learn more about each other's inspection programs. Some progress was made to increase mutual reliance on routine surveillance good manufacturing practices (GMP) inspection reports of manufacturing facilities for over-the-counter drugs. During the 18-month period, FDA and HC conducted four observational inspections, exchanged numerous inspection reports, and had monthly meetings to discuss information on inspection sites of common interest. This collaboration between FDA and HC has resulted in discussions on how the agencies can continue to learn from each other and look for additional opportunities to collaborate on a range of drug products and substances, as well as sites of interest in third countries. Future work in this area will occur in a variety of platforms, including Pharmaceutical Inspection Co-operation Scheme (PIC/S) as both FDA and HC are current active members, as well as potentially multi-lateral pilot programs to ensure the continued safety of pharmaceutical products crossing our borders. In addition, regulators will continue to share inspection schedules bilaterally and through the PIC/S and to promote leveraging of inspectional resources to maximize inspection coverage. As each program evolves, FDA and HC look forward to engaging with stakeholders in a number of upcoming local and international meetings.

#### Globally Harmonized System for Classification and Labelling of Chemicals

(Workplace Hazards): The effort to align and synchronize implementation of the Globally Harmonized System (GHS) was successful in aligning the workplace hazard communication regulations in Canada and the United States. As a result, both countries will require common label and safety data sheet information for hazardous chemicals, which will promote both workplace safety and international trade. It is expected that the system will be in place by both countries no later than June 2015. Stakeholders have been routinely engaged in the regulatory development process and stakeholder meetings will continue to be held as part of GHS implementation. Health Canada and the U.S. Department of Labor have established a Memorandum of Understanding that will promote ongoing collaboration on the implementation of GHS updates.

### **D ENVIRONMENT**

**Light-Duty Vehicle Emissions**: Since emission regulations in this sector were already highly aligned, this action item focused primarily on enhancing technical collaboration and work sharing to support the implementation and administration of the existing regulations. To support coordinated compliance efforts and reliance on each other's testing activities, Environment Canada (EC) and the U.S. Environmental Protection Agency (EPA) conducted emission correlation testing on the same test vehicle at their respective laboratories and shared the results. In addition, EC and the EPA shared results from compliance verification and in-use vehicle testing to enhance program coordination and effectiveness. Having successfully completed work on implementation of the light-duty vehicle emissions initiative under the initial RCC *Joint Action Plan*, EPA and EC will continue their active, ongoing collaboration on vehicle and engine emissions under the existing U.S.-Canada Air Quality Agreement.

**Locomotive Emissions:** Transport Canada (TC) and the U.S. Environmental Protection Agency (EPA) have made progress towards aligning efforts to address emissions from locomotives. Work has been initiated on alignment of proposed Canadian *Locomotive Emissions Regulations* for criteria air contaminants with regulations already in place in the U.S. In October 2012, TC and the EPA co-hosted a workshop with the Railway Association of Canada (RAC) and the Association of American Railroads, in which close to 50 industry experts participated. Canada and the United States are developing a joint Voluntary Action Plan to reduce Greenhouse Gas (GHG) emissions from locomotives. Work in this area builds on the Memorandum of Understanding signed in April 2013 between TC and the RAC that provides a framework for addressing emissions in the Canadian rail sector covering the 2011 to 2015 period.

**Air Pollutants:** As committed to under the RCC, Canada and the United States completed the necessary technical and scientific foundations required to inform and support consideration of an expansion of the Canada-U.S. Air Quality Agreement to include a Particulate Matter (PM) Annex. A transboundary particulate matter science assessment was completed and will be assessed by the Air Quality Committee (which administers the Agreement) in the Summer of 2014. Future work to further address transboundary air pollution will be carried out within the existing structure of the Air Quality Agreement.

### E CROSS-SECTORAL AREAS

Joint Approaches to Nanotechnology Regulation: Each country primarily regulates nanotechnology under their respective chemical regulations, and the bi-national technical team found that while there are some differences in data requirements and legislative processes, they both approach the science in the same way. As such, Canada and the United States adopted common nanotechnology Policy Principles for the regulation of nanomaterials to help ensure consistency for industry and consumers in both countries. The technical team worked closely with stakeholders to develop classification schemes and industrial use profiles.

**Small Business Lens**: Canada and the United States are working to reduce regulatory burden on small businesses by implementing tools and provisions that better integrate small business considerations in regulatory design. Officials came to a common understanding of each other's tools and provisions, namely implementation of Canada's Small Business Lens and the U.S. *Regulatory Flexibility Act*. Both countries are satisfied that there is a high degree of alignment between how Canadian and U.S. regulators can take the needs of small business into consideration when designing regulations. Going forward, these coherent approaches to integrating small business considerations into regulatory design can help support ongoing regulatory alignment efforts under the RCC.