



**CANADA-UNITED STATES**  
**REGULATORY**  
**COOPERATION COUNCIL**  
**JOINT ACTION PLAN**  
**PROGRESS REPORT**  
**TO LEADERS**

**DECEMBER 2012**

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## HIGHLIGHTS

As partners in the largest bilateral trading relationship in the world, and as part of highly integrated supply chains, individual Canadian and American firms move tens of thousands of shipments of goods back and forth across our shared border on a daily basis to access each other's market. Such shipments often experience impediments both at and behind the border because of the two nations' individual regulatory requirements.

It was in this context that Canada's Prime Minister Stephen Harper and United States President Barack Obama issued a Joint Statement on February 4, 2011, creating the Canada-United States Regulatory Cooperation Council (RCC) which subsequently issued the Joint Action Plan on December 7, 2011. In the year since this announcement, steady progress has been achieved in advancing regulatory cooperation between our two countries:

- **COMPLETED WORK PLANS:** In January 2012, draft Work Plans for each of the 29 initiatives set out in the Joint Action Plan were shared with interested stakeholders from both sides of the border at an RCC stakeholder engagement event held in Washington, D.C. Following stakeholder input and Canada-U.S. agency negotiations, all 29 Work Plans were completed and posted on the RCC's Canadian and American websites between March and July 2012.
- **EARLY DELIVERABLES:** After individual Work Plans were announced, implementation began. Early deliverables include steps to mitigate particular misalignments between Canadian and American regulations. Work is also underway on the development of Memoranda of Understanding, discussion papers, initial statements of work on regulatory changes and various assessment activities. Specific examples of regulatory cooperation progress achieved over the past year include:
  - the launch of pilot projects for simultaneous submissions to regulators in both countries for crop protection products;

- in the area of veterinary drugs, simultaneous reviews by regulators in both countries for three drug submissions;
  - initiation of a pilot project for the joint inspection of non-Canadian and non-U.S. flagged vessels entering the Great Lakes-St. Lawrence Seaway, focusing on security and pollution prevention, and monitoring living and working conditions for workers on these vessels; and
  - discussion of common policy principles that would guide an aligned approach to the regulatory oversight of nanotechnology and nanomaterials.
- **ONGOING ALIGNMENT MECHANISMS:** Efforts to implement the 29 Work Plans have underlined the importance of finding systemic solutions to avoid creating new regulatory misalignments. In pursuit of such ongoing regulatory alignment mechanisms, Canadian and American officials have begun discussions on how to formalize cooperation in their areas of responsibility.
  - **STAKEHOLDER ENGAGEMENT:** Stakeholders are engaging with the RCC on two levels: activities oriented toward regulatory cooperation in general, and those at a technical level with the Working Groups. Initial feedback indicates that stakeholders have been encouraged by the outreach, but that there is considerable room for additional engagement.
  - **EXECUTIVE ORDER 13609:** In May 2012, President Obama issued an Executive Order strengthening institutional mechanisms for facilitating international regulatory cooperation<sup>1</sup> and reflecting a commitment to regulatory cooperation going forward.
  - **RCC SECRETARIAT RELATIONSHIP:** Efforts to foster bilateral regulatory cooperation have cemented the relationship between RCC secretariat officials in Canada and the United States.

This Report provides an update on the progress that has been achieved over the past year.

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1. Executive Order 13609 (Promoting International Regulatory Cooperation) is available at [www.whitehouse.gov/sites/default/files/omb/infoereg/eo\\_13609/eo13609\\_05012012.pdf](http://www.whitehouse.gov/sites/default/files/omb/infoereg/eo_13609/eo13609_05012012.pdf).

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## DEVELOPING THE REGULATORY COOPERATION COUNCIL

On February 4, 2011, the newly created Canada-United States RCC was given the mandate to promote economic growth and job creation and provide benefits to our consumers and businesses through increased regulatory transparency and coordination.

Work between the two governments identified a diverse set of initiatives that are guided by key principles set out in the RCC Terms of Reference. These include the following:

- Each country maintains its own sovereign regulations – reliance on the other country’s system to inform one’s own decision making, and closer alignment of existing Federal regulatory systems, consistent with our respective domestic laws, are to be the focus.
- Regulatory outcomes for consumer protection, health, safety, security, and the environment are not to be compromised.
- New regulatory systems are to be designed with the goal of achieving regulatory alignment, to the extent feasible and appropriate. Regulatory alignment is to be sought for all future United States-Canada regulatory system development – with differences existing only where necessary and with the impacts considered.
- The role of the RCC is to be one of broad engagement, including bilateral and horizontal coordination and the generation of ideas to advance the implementation of these principles. Efforts toward regulatory alignment are to 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 regulatory differences, mechanisms to facilitate and secure future alignment are to be developed. Transparency and early engagement between the United States and Canada and with stakeholders are to underlie these efforts.
- Opportunities are to be pursued that provide benefits to both the United States and Canada.

On December 7, 2011, the RCC Joint Action Plan was launched, setting out 29 initiatives where the United States and Canada are to seek greater alignment in their regulatory approaches. The RCC Joint Action Plan represents a unique opportunity to contribute to a fundamental deepening of the regulatory relationship between Canada and the United States.

Senior Agency Officials from both countries lead the Working Groups. The Working Groups drafted Work Plans for each of the 29 initiatives. These Work Plans provide detailed action items to be accomplished within a two-year time horizon, stakeholder engagement opportunities throughout the process, and specific goals for considering systemic alignment.

This document serves as a report to leaders on the progress of implementing the RCC Joint Action Plan.

The Joint Action Plan is neither about creating a single regulatory system for both countries, nor for one country to make regulatory decisions on behalf of the other. Rather, it targets existing or emerging misalignments, and focuses on creating systemic mechanisms to secure regulatory alignment into the future.

The RCC's cooperation agenda does not encompass all aspects of both countries' regulatory systems. However, in areas where Canada and the United States have similar goals, similar systems, or similar regulatory approaches with respect to traded goods (final goods or intermediate inputs), the RCC is actively pursuing efforts to encourage Canadian and American regulators

to work in close cooperation on the technical aspects of a work agenda that will result in greater regulatory alignment. Although pursuing Canada-United States collaboration requires time and resources, the cost of not collaborating can be significant.

Decisions can be made to avoid unnecessary costs, bring jointly approved products to Canadian and U.S. consumers simultaneously, and maintain each country's sovereignty and high levels of health, safety, environmental protection, and privacy rights. This supports the effectiveness and efficiency of regulations, while providing benefits to businesses and consumers on both sides of the border. Costs can be reduced and time can be saved without compromising public health and safety if regulatory work is aligned.

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## KEY RCC MILESTONES

Steady progress has been achieved to date with respect to fostering Canada-United States regulatory cooperation via the RCC. The following is a summary of key events marking the RCC's efforts thus far.

- February 4, 2011 – Prime Minister Stephen Harper and President Barack Obama announced<sup>2</sup> the creation of the Canada-United States RCC.
- June 1, 2011 – Canada and the United States issued the Terms of Reference<sup>3</sup> outlining the mandate, principles and organization of the work to be performed by the RCC.
- August 29, 2011 – the Canadian RCC Secretariat released a publication entitled *Summary Report on Consultations with Canadians on Regulatory Cooperation between Canada and the United States*<sup>4</sup>.
- December 7, 2011 – Prime Minister Harper and President Obama released the Joint Action Plan for the Canada-United States Regulatory Cooperation Council<sup>5</sup>.
- January 30 and 31, 2012 – the RCC and its bi-national Working Groups facilitated stakeholder meetings<sup>6</sup> in Washington, D.C.
- May 1, 2012 – President Obama issued an Executive Order entitled *Promoting International Regulatory Cooperation*<sup>7</sup>.
- March through July 2012 – Work Plans<sup>8</sup> guiding the implementation of RCC Joint Action Plan initiatives were completed and posted on the Internet.

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2. Information about the February 4, 2011 public announcement regarding the creation of the RCC is available at [www.actionplan.gc.ca/eng/media.asp?id=4606](http://www.actionplan.gc.ca/eng/media.asp?id=4606).

3. The RCC's Terms of Reference are available at [www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=382](http://www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=382).

4. The RCC Canadian Secretariat's consultations summary report is available at [www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=377](http://www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=377).

5. The full *Joint Action Plan for the Canada-United States Regulatory Cooperation Council* is available at [www.actionplan.gc.ca/eng/feature.asp?pageId=381](http://www.actionplan.gc.ca/eng/feature.asp?pageId=381) in Canada and [www.whitehouse.gov/sites/default/files/us-canada\\_rcc\\_joint\\_action\\_plan3.pdf](http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf) in the United States.

6. Documentation pertaining to the January 30 and 31, 2012 RCC stakeholder events can be found at [www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=407](http://www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=407) in Canada and [www.trade.gov/rcc/stakeholder-outreach-summary.asp](http://www.trade.gov/rcc/stakeholder-outreach-summary.asp) in the United States.

7. President Obama's *Executive Order Promoting International Regulatory Cooperation* can be found at [www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation](http://www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation).

8. Completed RCC Work Plans can be accessed at [www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=397](http://www.actionplan.gc.ca/eng/feature.asp?mode=preview&pageId=397) in Canada and [www.trade.gov/rcc](http://www.trade.gov/rcc) in the United States.



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## WORK PLAN PROGRESS TO DATE

By the end of January 2012, draft Work Plans for the initiatives set out in the Joint Action Plan had been shared with interested stakeholders from each side of the border. The RCC organized a two-day stakeholder event on January 30-31, 2012, in Washington, D.C., inviting American and Canadian stakeholders to meet agency leads in person to provide input on the draft plans.

Following the January 2012 stakeholder session, and after considerable discussions and input between Canadian and U.S. agencies, final Work Plans were rolled out and posted on the RCC's Canadian and U.S. websites between March and July 2012<sup>9</sup>.

Final Work Plans touch upon a wide array of regulatory cooperation activities, including: technical/scientific collaboration, pilot programs, information sharing, mutual recognition, harmonized testing procedures, joint standards, and collaborating on common approaches to regulations. The Work Plans also include exploring mechanisms for ongoing collaboration that are designed to make unnecessary regulatory differences more unlikely in the future.

The pace and scope of the bilateral work have grown steadily. The following provides an overview of progress to date – divided by sector – including examples of specific early Work Plan deliverables.

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9. Then-OIRA Administrator Cass Sunstein remarked upon the posting of the final Work Plan in an online blog available at [www.whitehouse.gov/blog/2012/07/30/regulatory-cooperation-action](http://www.whitehouse.gov/blog/2012/07/30/regulatory-cooperation-action).

## A. AGRICULTURE AND FOOD

### FOOD SAFETY

#### INCREASE CANADA-UNITED STATES ALIGNMENT AND RELIANCE ON EACH OTHER'S FOOD SAFETY SYSTEMS

- **COMMON APPROACH TO FOOD SAFETY:** The Canadian Food Inspection Agency, Health Canada, the Public Health Agency of Canada and the U.S. Food and Drug Administration are working through a system recognition process as outlined in the RCC Work Plan “Common Approach to Food Safety.” Successful completion of this process may lead to closer regulatory partnerships and support the development of bilateral frameworks for information sharing. Work is underway to identify common food safety priorities as a first step toward deeper regulatory cooperation. It is anticipated that the framework will be presented to senior officials in January 2013.
- **EQUIVALENCE OF MEAT SAFETY SYSTEMS:** Due to a range of issues, progress on the underlying equivalence project has been slower than anticipated; however, in June 2012 the U.S. Food Safety and Inspection Service and the Canadian Food Inspection Agency agreed on Terms of Reference to guide high level engagement and ensure progress toward ongoing alignment of our meat safety systems.
- **MUTUAL RELIANCE OF FOOD TESTING RESULTS:** With a view to establishing mutual reliance on jointly acceptable food safety laboratory recognition criteria, test results and methodologies, an inventory of current processes and tools for food safety testing by each jurisdiction has been developed, and a gap analysis is targeted for completion by April 2013.
- **MEAT AND POULTRY PRODUCTS EXPORT CERTIFICATION:** Both the U.S. Food Safety and Inspection Service and the Canadian Food Inspection Agency have undertaken independent internal reviews of their own import and export requirements to identify redundancies and anticipate areas where progress can be made to reduce these inefficiencies. These independent reviews will set the stage for further bilateral discussions in early 2013. Work on this front is still in its initial stages and has not advanced as quickly as anticipated.

## AGRICULTURAL PRODUCTION

### FURTHER INCREASE SYMMETRY AND ACCESS WITH RESPECT TO AGRICULTURAL PRODUCTION

- **CROP PROTECTION PRODUCTS:** To facilitate more equal access to effective means of pest control in both countries, pilot projects are underway to remove obstacles to, and encourage joint submission of, use-expansions and fully aligned labels, and to develop joint guidelines and aligned data collection processes and procedures for residue trials. To date, comparative analysis of each country's registration processes to identify areas of misalignment and the development of a joint form for product specification have been initiated. Work has begun on efforts to explore how combining an increased number of minor crop uses and a review of associated import maximum residue levels/tolerance levels could further encourage simultaneous submissions to Canada and the United States, using the pesticide spirotetramat as an initial test case.
- **VETERINARY DRUGS:** The U.S. Center for Veterinary Medicines and Health Canada's Veterinary Drugs Directorate have agreed on an approach for simultaneous reviews of technical sections of drug applications. Pilot reviews have been launched to test the approach and one of the pilot drug applications was near-simultaneously approved on both sides of the border.
- **PERIMETER APPROACH TO PLANT PROTECTION:** A framework for a Canada-United States perimeter approach to plant protection is under development by the regulatory agencies. Pilot projects to enhance the concepts of a perimeter approach are underway in two areas: coordinating approaches to regulatory oversight for Chrysanthemum White Rust and streamlining the commodity certification process for the Greenhouse Certification Program. The pilot projects will inform how to work toward increased consistency, where appropriate, between Canadian and U.S. import requirements related to plant health risks, increased communication and cooperation between the two countries, and the development of equivalent or harmonized plant quarantine systems that include programs and their implementation.

- **ZONING FOR FOREIGN ANIMAL DISEASES:** An arrangement for the mutual recognition of zoning decisions in the event of a highly contagious foreign animal disease outbreak – to collectively protect both countries from disease while allowing for continued bilateral trade from areas located outside of the disease control and eradication zone(s) – has been developed and signed by both parties. In support of this Work Plan, efforts are underway to develop an ongoing framework to implement the protocol.

## MARKETING

### INCREASE FAIRNESS AND EFFECTIVENESS OF AGRICULTURE AND FOOD TRADE

- **MEAT CUT NOMENCLATURE:** A review of nomenclature regimes in both countries, including differences and impediments to a common approach and priority areas for further work, has been completed in collaboration with stakeholders. With a view toward possible mutual reference of the Institutional Meat Purchasing Specifications, which are voluntary consensus specifications for meat products maintained by the U.S. Department of Agriculture's Agricultural Marketing Service, the Canadian Food Inspection Agency and industry officials will collectively participate in the standards development process.
- **FINANCIAL PROTECTION TO PRODUCE SELLERS:** Agriculture and Agri-Food Canada (AAFC) and the U.S. Agricultural Marketing Service have completed the information gathering phase of a process to develop Canadian industry tools supported by regulation for sellers of fresh produce that are comparable to those available in the United States. Fresh produce industry stakeholders in both countries have been engaged in the identification of options to secure more effective contract management and licensing of fresh produce buyers, as well as regulatory measures that could be adopted to better ensure industry payment to fresh produce sellers in cases of buyer bankruptcy and insolvency. AAFC, in consultation with the Canadian Food Inspection Agency and Industry Canada, will next undertake an analysis of the feasibility of those options including the necessary measures that would be required to implement them. The Government of Canada will continue to engage stakeholders and will announce its decision by March 2013.

## B. TRANSPORTATION

### SURFACE (ROAD AND RAIL)

#### INCREASE JOINT STANDARDS DEVELOPMENT AND ALIGNMENT

- **EXISTING MOTOR VEHICLE SAFETY STANDARDS:** Opportunities for greater alignment of specific existing standards in the areas of occupant protection, side impact, and ejection mitigation have been studied and a report has gone out for stakeholder feedback. Officials are in the process of identifying research and regulatory priorities for additional alignment work. Canada published proposed harmonized tire regulations and proposed frontal impact occupant protection regulations in the Canada Gazette<sup>10</sup> in February 2012.
- **NEW MOTOR VEHICLE SAFETY STANDARDS:** Collaborative research and joint regulatory work in advance of formal proposal development, with the ultimate goal of aligned regulations and testing procedures for electric vehicle safety, hydrogen vehicle safety, and quiet vehicle pedestrian safety (for electric and hybrid-electric vehicles), are underway. Collaboration on potential safety issues related to clean technologies are also underway, which may lead to the development of consumer awareness guidelines, standards or regulations.
- **INTELLIGENT TRANSPORTATION SYSTEMS:** A bi-national Working Group conducted a series of consultations with key stakeholders, and a deployment plan has been established for the implementation of border wait-time measurement systems. (This work also supports the Beyond the Border initiative on border wait time.) Installations have been completed at the Queenston-Lewiston (Niagara Falls) and Peace (Fort Erie-Buffalo) bridges. Work on outreach, coalition building, analysis and planning is underway with facility owners of the remaining top 20 crossings that are un-instrumented or partially instrumented. Transport Canada, the U.S. Department of Transportation, and the Association of State Highway and Transportation Officials have agreed to conduct a project on the subject related to the North American deployment of Connected Vehicles systems. The project will analyze roadside and other communications infrastructure needs, including specific cross-border requirements.

10. The proposed harmonized tire regulations and frontal impact occupant regulations are available in the Canada Gazette at: <http://canadagazette.gc.ca/rp-pr/p1/2012/2012-02-11/html/reg3-eng.html>.

- **RAIL SAFETY STANDARDS:** Canadian and U.S. regulators continue safety-related discussions focused on best practices and exploring alignment opportunities in the areas of risk reduction programs; high speed rail equipment standards; positive train control systems amendments; medical guidelines for certified engineers and conductors; and critical incident stress plans. Furthermore, a Memorandum of Cooperation between Transport Canada and the U.S. Federal Railroad Administration, outlining a joint cooperation framework to promote regulatory alignment, is currently under development.

## MARINE

### INCREASE ALIGNMENT AND RELIANCE ON EACH OTHER'S SYSTEMS

- **REGULATORY OVERSIGHT REGIME ON THE GREAT LAKES AND ST. LAWRENCE SEAWAY:** Work began in October 2011 on the possible expansion of the Joint Initial Verification Program to address security and safety inspections related to foreign vessels entering the St. Lawrence Seaway and Great Lakes System. This has allowed for joint safety inspections, which in turn reduce the amount of time a ship is inspected within the System. To explore the feasibility of mutual recognition of regulatory oversight regimes, a Port State Control Pilot Project – which includes joint inspections by Transport Canada and the U.S. Coast Guard officials – has begun for vessels before they enter the St. Lawrence Seaway and Great Lakes System and includes coordinated targeting, joint inspection, mutual recognition of inspection results, and information sharing.
- **MARINE TRANSPORTATION SECURITY REGULATIONS:** Transport Canada and the U.S. Coast Guard are currently working to align marine transportation security requirements to prevent duplication of services and to remove impediments to cross-border trade. Work continues to align the Canadian definition of Certain Dangerous Cargoes with that of the United States and to include a reference to Alternative Security Arrangements in Canadian regulations. In addition, a Memorandum of Understanding between Transport Canada and the U.S. Coast Guard, to facilitate the establishment of lasting and ongoing marine safety and security cooperation mechanisms, was signed in June 2012.

- **CONSTRUCTION / SAFETY STANDARDS FOR SMALL CRAFT:** Collaborative work between Transport Canada and the U.S. Coast Guard to align regulations and standards for construction of pleasure craft / recreational boats, to align a compliance monitoring program, and to develop a joint safety defect and recall program has been undertaken and is now in the review stage. The draft proposal will be finalized once all input has been received. Regulators are also reviewing elements of an ongoing alignment framework that would align standards, compliance monitoring, and safety recall approaches into the future.
- **LIFE SAVING APPLIANCES:** Transport Canada and the U.S. Coast Guard have been progressing, in cooperation with industry stakeholders, on the development and approval of a harmonized Canadian-U.S. standard for lifejackets under an accredited consensus standards development process. Initial discussions on the development of a bilateral cooperative framework to ensure continued alignment have drawn on previous U.S. experience with the European Union as a model of the processes involved and resources required, providing a context to begin exploring possible next steps.

## OTHER TRANSPORTATION ISSUES

- **ALIGNMENT OF DANGEROUS GOODS MEANS OF CONTAINMENT:** A framework to allow mutual recognition of each country's regulation of gas cylinders and tank trucks has been developed. This includes regulatory mechanisms that recognize equivalent levels of safety that have been achieved by the other regulatory system. A Memorandum of Cooperation between the United States and Canada on the Safe Transportation of Dangerous Goods was signed in September 2012 in this regard. In addition, Transport Canada has been progressing on the development of approvals that will be aligned with a Hazardous Materials Guidance Document issued by the U.S. Department of Transportation. These approvals will facilitate the movement of dangerous goods by rail between Canada and the United States.

- **UNMANNED AIRCRAFT SYSTEMS:** With a view to developing an overall mechanism to align regulatory approaches, Canadian and American regulators have agreed to a protocol for the sharing of information on the civilian use of unmanned aircraft systems (UAS). Given that both countries are in the early phases of developing UAS policies and the relevant regulatory frameworks, the two countries have held discussions to share broad experiences, and to identify potential common issues related to developing future operator certificate and type certification parameters.



## C. ENVIRONMENT

### BETTER SYNCHRONIZE IMPLEMENTATION OF REGULATIONS AND LEVERAGE EXISTING EXPERTISE IN EACH OTHER'S REGULATORY SYSTEMS

- **LIGHT-DUTY VEHICLE EMISSIONS:** To support coordinated compliance efforts, Environment Canada and the United States Environmental Protection Agency have commenced emission correlation testing in concert with various emission laboratories and have begun to share test results with program partners. In support of this Work Plan, and based on feedback from the Canadian automotive industry, Environment Canada intends to amend the reporting requirements under its greenhouse gas emission regulations for light-duty vehicles to address areas of incompatibility with those in the United States and to reduce administrative burden.
- **LOCOMOTIVE EMISSIONS:** A review of technology and infrastructure for reducing greenhouse gas (GHG) emissions in the rail sector has been completed. Efforts to date have focused on the joint development of options for reducing GHG emissions from locomotives, which could possibly include the development of voluntary GHG emission reduction targets, operating measures, technology improvements and fleet change actions as areas for future work.
- **PARTICULATE MATTER (AIR POLLUTANTS):** Joint scientific work is underway to assess the cross-border movement of particulate matter, an air pollutant most commonly associated with smog and premature mortality, with a view to considering the expansion of the *Canada-U.S. Air Quality Agreement*. Recent scientific work has focused on the joint consideration of preliminary data for the update of the 2004 particulate matter science assessment of the trans-boundary movement of particulate matter.

## D. HEALTH AND PERSONAL CARE PRODUCTS AND WORKPLACE CHEMICALS

**FURTHER ALIGN REGULATORY REQUIREMENTS AND FURTHER LEVERAGE EACH OTHER'S REGULATORY CAPACITY, AND IMPROVE EFFECTIVENESS AND TIMELINESS OF PRODUCT APPROVALS.**

- **COMMON ELECTRONIC SUBMISSION GATEWAY:** The electronic submission gateway is the foundation that will allow for increased review collaboration between the two regulatory agencies. In terms of project progress, the technical requirements and operational concept review in support of the creation of a Canadian node on the U.S. Electronic Submission Gateway<sup>11</sup> has been completed and a service agreement allowing the U.S. Food and Drug Administration to implement the node on Health Canada's behalf is pending approval. When in place, this will allow companies to make online regulatory submissions (e.g. marketing applications / market authorizations for approval of pharmaceutical products) to Health Canada as they currently can to the Food and Drug Administration.
- **OVER-THE-COUNTER THERAPEUTIC PRODUCTS APPROVAL AND LICENSING (COMMON MONOGRAPHS):** Regulators have developed criteria for selecting a pilot monograph and are engaged in regulatory and scientific discussions on how to align such monographs (i.e. descriptions of the properties, claims indications, and conditions of use). A selected pilot project, on which both regulators plan to work cooperatively, will be included in the U.S. Unified Agenda of Federal Regulatory and Deregulatory Actions.
- **GOOD MANUFACTURING PRACTICES:** Health Canada and the U.S. Food and Drug Administration have exchanged inspection reports on Canadian manufacturing facilities for drugs and personal care products in order to assess each other's respective regulatory systems, operational frameworks, and drug establishment inventories / facility lists. Health Canada and the Food and Drug Administration are exchanging inspection reports for selected facilities that were inspected by both Agencies in order to undergo an assessment to determine comparable inspection coverage. Both agencies are in the final process of selecting manufacturing sites in each country where observational inspections will be conducted and compared as a step towards increasing mutual reliance on each other's routine surveillance work.

11. The U.S. Electronic Submission Gateway is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. [www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165573.htm](http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165573.htm).

- **GLOBALLY HARMONIZED SYSTEM (GHS) FOR CLASSIFICATION AND LABELLING OF CHEMICALS (WORKPLACE HAZARDS):** Health Canada and the U.S. Occupational Safety and Health Administration are in the process of finalizing and signing a Memorandum of Understanding to develop a joint process to coordinate and synchronize their implementation of common classification and labelling requirements for workplace hazardous chemicals on an ongoing basis. A small Working Group has also been established between the two agencies to ensure ongoing coordination of input for the United Nations Sub-Committee of Experts on the GHS.

## E. CROSS-SECTORAL AREAS

- **NANOTECHNOLOGY:** As a step to developing aligned approaches on foundational regulatory elements, Canada's efforts to date have focused on the development of common policy principles consistent with those in the United States for the regulation and oversight of actual and emerging applications of nanotechnology and nanomaterials. Both jurisdictions have also initiated a joint review of current risk assessment and risk management practices involving industrial nanomaterials under the *Canadian Environmental Protection Act 1999*, and the U.S. *Toxic Substances Control Act*. Stakeholders have been invited to propose specific joint pilot projects to examine Canadian and U.S. risk assessment / risk management practices and approaches for nanomaterials.
- **SMALL BUSINESS LENS:** Canada and the United States are committed to sharing best practices and enhancing the ways in which they assess and account for the special circumstances of small business in our respective regulatory processes. The Government of Canada announced the details of its regulatory Small Business Lens on October 1, 2012, which requires regulators to assess and, where possible, mitigate the impact of regulations on small business. The two countries have shared approaches and tools that they use to assess and account for the needs of small businesses when developing regulations. Best practices are being identified and will be further shared in order to gain from lessons learned on both sides of the border.

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## BENEFITS OF REGULATORY COOPERATION

Although there is limited quantified information on the benefits of regulatory cooperation in general, and the work of the RCC more specifically, it is clear that regulatory alignment and ongoing cooperation ultimately benefit consumers, producers and regulators, including by improving:

- 1. MANUFACTURING SECTOR COMPETITIVENESS AND WHOLESALE / RETAIL SECTOR EFFICIENCY:** Synchronized approvals and aligned standards can reduce production costs of Canadian and American companies, enhance our competitiveness, and facilitate bringing products to market.
- 2. REGULATORY EFFICIENCY AND EFFECTIVENESS:** Working together, Canadian and American regulators can achieve shared goals of ensuring health, safety, and environmental protections more efficiently and effectively. Regulators on both sides of the border can avoid duplicating work and save time and money by, for example, sharing work when addressing common regulatory challenges with third countries and combining specialized expertise when approving products, developing regulatory standards, and conducting inspections.

In a more aligned system:

- Regulations designed to ensure health, safety, and environmental protections benefit from the combined expertise of Canadian and U.S. regulators;
- Products that are approved through more aligned regulatory processes are expected to be available in both markets almost simultaneously; and
- Any efficiencies achieved through aligned and shared work can be directed to address other risks, including risks posed by third countries.

To better estimate the specific benefits of Canada-U.S. regulatory cooperation, the RCC has begun work with individual stakeholders drawn from some of the relevant sub-sectors of the economy, including vehicle manufacturing, agriculture, pharmaceuticals, and biotechnology.

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## ONGOING SYSTEMIC REGULATORY ALIGNMENT MECHANISMS

The RCC is taking bold steps toward challenging the status quo and looking at new, systemic approaches to bilateral regulatory cooperation. The RCC Terms of Reference and Joint Action Plan encourage the development of ongoing regulatory alignment mechanisms, and they are included in most of the Work Plans as a distinct deliverable. Ongoing mechanisms should lead to significant cooperative work and the reduction or elimination of unnecessary regulatory misalignments. The various Working Groups have begun to identify common challenges and potential solutions that should lead, over time, to such mechanisms.

The regulatory communities of Canada and the United States are up to this challenge. Such efforts require greater coordination and teamwork, but the benefits can be significant. Since the two countries share common regulatory objectives, and face similar risks from domestic and external sources, addressing these issues collaboratively strengthens the regulatory system overall. In several areas of regulatory business in specific sectors, there are opportunities to develop systemic alignment mechanisms, including in regulatory standard-setting, cooperation in product reviews, approvals, and systems reliance, and managing third country import risk. Joint work in these areas is still in its infancy and is being explored as U.S. and Canadian regulators implement the Joint Action Plan. Moving forward, Canada and the United States intend to identify opportunities for greater cooperation that, if undertaken in a systemic way, would serve to secure greater alignment between our countries' regulatory systems.

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## CONTINUING WORK

Much work has been accomplished in the last twelve months since the RCC Joint Action Plan was announced; however, much work remains to achieve the full potential of the RCC. Agencies are to implement the action items in the Work Plans, engage stakeholders, and report regularly on progress.