

## **CANADA- UNITED STATES REGULATORY COOPERATION COUNCIL NEWS DECEMBER 2013**

Welcome to a special edition of the Canada-U.S. Regulatory Cooperation Council (RCC) news update. This marks the two year anniversary of the release of the Joint Canada-United States Regulatory Cooperation Council Action Plan. These newsletters are prepared periodically to provide you with information on RCC plans, progress being made and other items of interest. Work will continue through the spring of 2014 on the initial Action Plan, and we will continue to provide you with updates on progress.

### **THANK YOU FOR YOUR INPUT**

From August 30 to November 8, 2013 stakeholders and citizens were invited to provide Canadian and American RCC officials with their views on how best to advance the way in which Canada and the United States work together to secure regulatory alignment.

We received tremendous response. Over 100 thoughtful and idea-provoking submissions were provided by 160 stakeholders representing all sectors and regions of both countries. The responses were overwhelmingly supportive of advancing Canada-U.S. regulatory cooperation, signaled a strong desire for further work and included suggestions for another phase of RCC activity. Many specific ideas on how to strengthen and institutionalize Canada-U.S. regulatory cooperation were received.

This input will be incorporated in discussions over the coming months on next steps between Canada and the United States at the RCC Secretariat and departmental-levels. We will continue working with Departments/agencies and stakeholders and anticipate outlining our forward plan in the spring of 2014.

### **PARTICIPATE IN RCC WORKING GROUP WEBINARS**

Starting in January 2014, Canada and United States (U.S.) working group leads will hold joint webinars to allow stakeholders more opportunity to simultaneously interact on RCC issues with the officials from both countries. These webinars will provide updates on work plan progress, and allow you to directly engage with leads and technical staff. These webinars will begin on January 6 and be held regularly thereafter. They respond to stakeholder requests for more frequent engagement and facilitate the involvement of regionally-based firms and associations or others who may not be able to attend outreach and engagement meetings in person.

An initial schedule of all of the RCC webinars has been posted on the RCC websites ([www.trade.gov/rcc](http://www.trade.gov/rcc) and [RCC Action Plan Webinars | Canada's Economic Action Plan](#)), It will be updated regularly. Instructions on how to connect and actively participate in these on-line events are also available there.

## **PROGRESS ON INITIAL WORK PLANS CONTINUES**

Highlights of our recent and ongoing work include:

### **AGRICULTURE AND FOOD**

- The Canadian Food Inspection Agency (CFIA) and United States Animal and Plant Health Inspection Service (APHIS) completed consultations on [the draft Canada-United States Perimeter Approach to Plant Protection framework document](#) at the end of September. Analysis of stakeholder feedback is now underway and the framework will be reviewed and updated in light of comments received.
- A draft guidance framework for implementing the Canada-U.S. zoning protocol (being prepared as part of the Zoning for Foreign Animal Disease work plan) is expected to be released for comment in the new year. This framework will provide guidance to officials implementing the zoning protocol announced in January, 2013.
- Canadian industry led four Canada-U.S. stakeholder meetings over the past six months to examine proposed tools to provide financial protection to fresh produce sellers. The Canadian Food Inspection Agency (CFIA) undertook broad consultations on a regulatory framework for the Safe Food for Canadians Act (SFCA). The consultation included questions on whether industry should provide arbitration of fair trade practices for fruit and vegetable dealers and whether the Dispute Resolution Corporation (DRC), created under NAFTA, should be the single entity for this function. It also included a proposal that mandatory membership for fresh fruit and vegetable dealers in the DRC replace the current dual system of CFIA produce licence or DRC membership. In the coming weeks, Agriculture and Agri-Food Canada (AAFC) with the CFIA, will engage with Canadian and U.S. stakeholders on elements of a single dispute resolution body (e.g., membership, contract requirements, arbitration process and financial security requirements) that would ensure its effectiveness as a risk mitigation tool. The results of these discussions, combined with the results of CFIA's consultation, will inform the development of SFCA regulations next spring. AAFC also continues to work with stakeholders to explore other potential risk mitigation measures that could increase sellers' ability to recover payment in instances of buyer insolvency/bankruptcy.
- Under the Common Approach to Food Safety work plan, CFIA, Health Canada and the Public Health Agency of Canada are preparing Canada's draft systems-recognition assessment report on the U.S. food safety system. Canada and the U.S. are aiming to exchange draft system recognition assessment reports early in the new year. If the assessments are favorable, the results will inform a systems recognition arrangement between the United States Food and Drug Administration (U.S. FDA) and Canada that

will strengthen our existing bilateral regulatory partnership to enhance cooperation and information exchange between Canada and the U.S..

- Mutual Reliance on Food Testing Results: CFIA and the U.S. FDA completed a gap analysis to identify differences among lab accreditation criteria used by regulators and consulted with stakeholders on the findings of the gap analysis. Based on this work, guiding principles are being drafted to inform the development of a permanent mechanism for the mutual acceptance of laboratory accreditation.
- Following the completion of the first joint review of a veterinary drug product by Health Canada and the U.S. FDA in December 14, 2012, six additional pilot product reviews have been initiated. Based on the experience gained during these projects, Canada and the US will share lessons learned and determine the way forward for ongoing alignment early in 2014.
- Health Canada's Pest Management Regulatory Agency (PMRA) and the US Environmental Protection Agency (EPA):
  - o have successfully completed a pilot project for use expansion registration of minor use crops. This has resulted in fully aligned labels and harmonized Maximum Residue Levels (MRLs) eliminating potential trade barriers and allowing for shorter review times for import MRLs. Importantly, the two organizations have agreed to mutual principles for use in future joint review projects;
  - o agreed to the content of the draft joint Confidential Statement of Product Specifications (CSPS) form. In addition, they are conducting a pilot project to populate new forms using existing data and have begun discussions on the development of an electronic tool and shared portal. A joint Information Technology strategy is underway to harmonize business rules, in order to collaborate on submission formats and forms on all registration actions;
  - o are working to manage differences in timelines for joint review projects, and have completed the analysis of the regulatory timelines for pesticide actions in both organizations. This analysis has identified opportunities to maximize the alignment of review timelines for future submissions;
  - o are working towards joint guidelines for residue field trials. The two organizations have agreed upon the use of the proportionality concept and continue to develop harmonized crop groupings, resulting in the need for less residue data to support a greater number of crops on both sides of the border; and
  - o initiated a pilot project on development and use of harmonized report templates for residue trials. Differences have been identified in the study protocols, data collection, and templates. Adjustments are being made to align the tools where feasible and the organizations are aligning research initiatives, including 18 joint projects in 2013.

## HEALTH AND PERSONAL CARE PRODUCTS

- The Common Electronic Submission Gateway (CESG) pilot was completed between the U.S. FDA and Health Canada in October 2013. A gradual on-boarding phase began in November 2013 with Canadian industry pilot participants using the CESG to submit documents for selected types of regulatory activities, for example, industry responses to Health Canada clarifications of submissions in electronic Common Technical Document (eCTD) format. After January 2014, the CESG will be made generally available for these activities. Going forward the CESG may be expanded to include other regulatory activities and serve as the foundation for increased collaboration on the review of drug products by the two regulatory agencies.
- Health Canada and the U.S. FDA have conducted observational inspections of pharmaceutical manufacturing sites in Canada and the U.S. These were undertaken as part of the work to enhance collaboration on compliance and enforcement by increasing mutual reliance on each other's routine surveillance of good manufacturing practices (GMP). Inspection assessment reports have been completed and a final report for all observational inspections is being compiled. The final report will outline the similarities and differences between the agencies' practices in an effort to identify gaps, if any, and facilitate future reliance.
- Work has continued on the pilot initiative under the RCC Common Monographs work plan, the first of its kind between Health Canada and the U.S. FDA. The working group selected common cold indication for certain over-the-counter antihistamine ingredients as its [pilot](#). The working group is currently finalizing respective documents for internal approval, including aligned monograph elements such as directions, warnings, indications, and conditions of use. Health Canada and the U.S. FDA plan to publish their respective draft monographs for comment in 2014.

## TRANSPORTATION

- On [November 20, 2013](#), Transport Canada announced important regulations to enhance the safety of tires manufactured for the Canadian market. These regulations will replace the current Motor Vehicle Tire Safety Regulations, 1995 (MVTSR, 1995). Consistent with RCC principles, the regulations also align Canadian requirements for winter tires with those of the U.S. This allows the enforcement of winter tire standards if manufacturers choose to use the peaked mountain with a snowflake symbol. By implementing these regulations, the Government of Canada is responding to tire and vehicle manufacturers who have encouraged the government to align Canadian tire safety regulations with those of the United States.
- On [November 16th](#), Transport Canada published proposed regulations in Part I of the Canada Gazette titled: "Regulations amending the Transportation of Dangerous Goods Regulations (Update of Standards)" which propose to adopt new and revised standards pertaining to the selection, design and manufacture of means of containment used in the transportation of dangerous goods. The proposal would allow for mutual recognition of United Nations standard pressure receptacles (UN cylinders),

and recognition of inspection under U.S. requirements for highway tanks which would reduce administrative burden on industry.

## **OTHER**

- Consistent with Canada's commitments under the RCC, on [October 4, 2013](#), Natural Resources Canada announced a proposed amendment to Canada's energy efficiency standards for light bulbs to provide greater choice and lower costs for consumers and align with standards in the U.S. This change will reduce the administrative burden and costs associated with distribution as companies will not need to differentiate between American and Canadian markets.

## **ENGAGING WITH STAKEHOLDERS**

### **ONGOING CONSULTATIONS AND UPCOMING EVENTS**

- The Canada-U.S. RCC Nanotechnology Working Group's final stakeholder workshop will be held in Washington, D.C. on January 14<sup>th</sup>, 2014. At this workshop, officials will report on results of completed work and discuss future ongoing engagement between the two countries and stakeholders.

### **RECENT EVENTS AND ENGAGEMENTS**

- On November 4 and 5, 2013, the Canada American Business Council hosted a policy conference in Ottawa: *Blueprint for the Future of Canada/US Relations*. Senior RCC officials participated and provided an update on the work of the RCC.
- During October and November 2013, officials from the Canadian RCC Secretariat met with and participated in events with stakeholders from a number of organizations including the National Cattle Feeders Association, the Canadian Paint and Coatings Association, the Canadian Association of Importers and Exporters, the Canadian Vehicle Manufacturers Association and the Global Automakers of Canada.
- Senior RCC officials continue to meet individually and collectively with business and community stakeholders in Canada and the U.S.

## TO STAY CONNECTED OR FOR MORE INFORMATION

Working Groups for the individual RCC Joint Action Plan initiatives continue to be committed to consulting with, and providing information to, stakeholders. Contact information can be found at the bottom of each of the individual work plan on our website.

- Work Plans for each of the Joint Action Plan's 29 initiatives: [www.actionplan.gc.ca/page/rcc-ccr/initiatives-and-working-groups](http://www.actionplan.gc.ca/page/rcc-ccr/initiatives-and-working-groups)

For general information please visit our website or send us an email at:

- Website: [www.actionplan.gc.ca/RCC](http://www.actionplan.gc.ca/RCC)
- Email: [rcc-ccr@pco-bcp.gc.ca](mailto:rcc-ccr@pco-bcp.gc.ca)

## RCC REFERENCE DOCUMENTS

- [RCC News – October 2013](#)
- [RCC News – May 2013](#)
- [Canada - U.S. Regulatory Cooperation Council Joint Action Plan Progress Report to Leaders](#) (December 2012)
- [U.S. Executive Order 13609](#) promoting international regulatory cooperation (May 1, 2012)
- [RCC Joint Action Plan](#) (December 2011)
- [What Canadians Told Us: A Report on Consultations on Regulatory Cooperation Between Canada and the United States](#) (August 2011)

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