

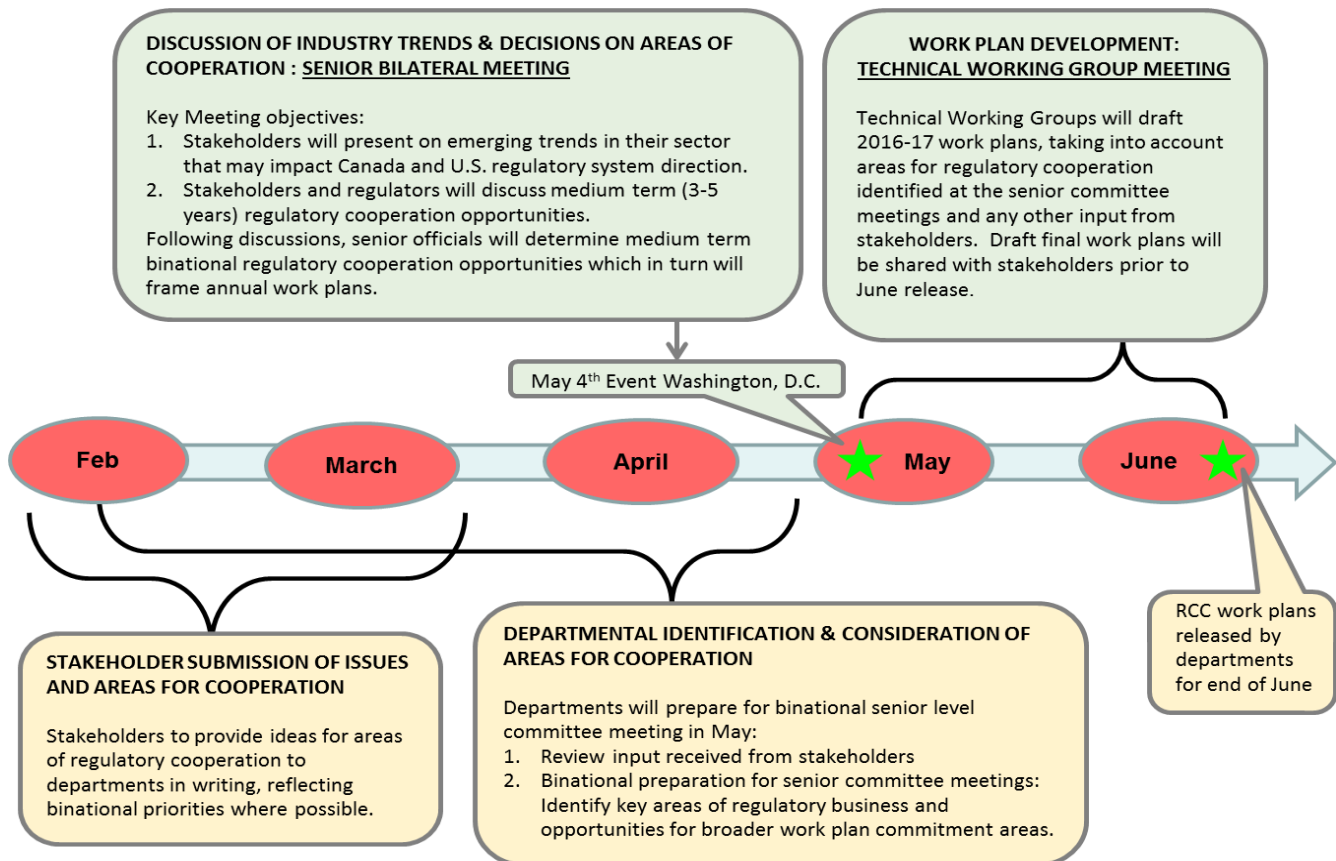
CANADA-UNITED STATES REGULATORY COOPERATION COUNCIL NEWS

MARCH 2016

Canada-United States (U.S.) Regulatory Cooperation Council (RCC) news updates are shared periodically to provide you with information on RCC plans, progress and other items of interest. This update includes information on 2016/2017 work planning as well as considerations for [stakeholder submissions of ideas](#) for Canada-U.S. regulatory cooperation. Information on Canada-U.S. departments and agencies' [progress on annual work plans](#) (WP) and other regulatory cooperation-related activities are also included in this update.

2016/2017 REGULATORY COOPERATION WORK PLANNING PROCESS

The following provides a summary of information on the 2016/2017 regulatory cooperation work planning process that is now underway:



Stakeholders should now be preparing input for the 2016/2017 work planning process. It is important to note however, that input can be developed and submitted to regulatory departments at any time throughout the year. Work plans are evergreen and can be updated by regulators to reflect emerging priorities and issues.

STAKEHOLDER SUBMISSION OF IDEAS FOR CANADA-U.S. REGULATORY COOPERATION

Input from stakeholders is key to identifying and elaborating opportunities related to regulatory cooperation between Canadian and U.S. regulators. The following summary is intended to help stakeholders better frame their input to assist decision making by regulators.

When preparing a RCC submission for departments or agencies, best practices could include: clearly describing how the idea or issue falls within the scope of regulatory cooperation work; outlining any considerations relating to the alignment of the regulatory work, and identifying the benefits and cost of the opportunity.

Scope of work

Submissions should identify how the idea being brought forward falls under the scope of regulatory cooperation. Opportunities being presented should pertain to regulatory matters in areas where cooperation is desirable for both countries. Areas of work for regulatory cooperation can include reliance on outcomes achieved in the other jurisdiction, standard setting, product reviews and approvals, managing risk at the Canadian and U.S. perimeter, etc. It can also include the programs and procedures used to implement a regulation and the related requirements.

It is also beneficial to provide any additional context that explains upcoming changes in the sector that are creating a new opportunity for regulatory cooperation. Describe what the change is and how this change creates an opportunity for both countries to align their regulatory systems. This description will then inform the identification of how and when the regulatory approaches can align and what the potential benefits and costs would be in both countries.

Alignment

Submissions should clearly outline when an aligned regulatory approach is desired. This refers to how Canada and the U.S. might organize themselves, as well as how Canada and the U.S. could consider efforts in a global context.

Examples of considerations relating to cooperation on regulatory work might be: a forthcoming regulatory decision in one country that would create unnecessary differences if not taken into account and/or acted upon by the other country before it comes into force; coordinating updates to programs, procedures or regulations; or, supporting efforts between Canada and U.S. regulators in international and regional venues.

Benefits

Stakeholders are best placed to understand the impacts of regulatory cooperation. They possess detailed knowledge of their sector that allow for descriptions of manufacturing or supply chain impacts, which can inform departmental decision-making on the design and delivery of regulations. To help regulators better understand the magnitude and priority of an issue and its associated benefits and costs, submissions should include impacts related to both regulated parties and consumer benefits.

- Consumer benefits may include: increased product choice; timelier market availability; potential cost impacts; product quality; etc.
- Regulated party benefits may include: elimination of duplicative requirements, single submission processes, simultaneous market approvals, etc. In those situations where the impact can be quantified, estimates would be highly useful and should be provided.

Submission of ideas

Stakeholders in both countries should work together to submit jointly agreed upon regulatory cooperation ideas to regulators. Submissions should be directed to the relevant departments and agencies in both countries, and copied to the Canadian RCC Secretariat. Canadian department or agency contact information can be found at <http://pco-bcp.gc.ca/rcc>.

CANADA – U.S. DEPARTMENTS AND AGENCIES CONTINUED WORK ON REGULATORY COOPERATION

Following the release of bi-national work plans in May 2015, progress continues with Canadian and U.S. regulators across a number of sectors. Department and agency WPs can be found via web links at <http://pco-bcp.gc.ca/rcc> or <http://trade.gov/rcc>

Pesticides

Agencies: Health Canada's Pest Management Regulatory Agency (PMRA), U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP).

A priority issue is the Canada–U.S. joint re-evaluation of neonicotinoid pesticides, through the Pollinator Protection and the Neonicotinoid Pesticides initiative. The PMRA and the EPA have aligned their schedule for the re-evaluation of neonicotinoids. On January 6, 2016, a joint progress report and the first preliminary pollinator risk assessment were published.

Work is also progressing on the following initiatives:

- IT Solutions for submission of registration applications and information
- Template for Product Chemistry Reviews.

Pharmaceuticals and Biologics

Agencies: Health Canada (HC), U.S. Food and Drug Administration (FDA)

On November 12, 2015, HC and the FDA co-hosted the second joint public consultation meeting on International Council on Harmonisation of Technical Requirements for Registration

of Pharmaceuticals for Human Use (ICH) guidelines currently under development. Stakeholders' comments will be considered in ICH guideline development. The next joint FDA-HC public consultation meeting will take place in Spring 2016.

Medical Devices

Agencies: Health Canada (HC), U.S. Food and Drug Administration (FDA)

In June 2015, HC expanded the scope of electronic labelling for medical devices in order to better align with that of the FDA. This enables manufacturers to provide directions for use electronically for devices that are not sold to the general public.

Consumer Health Products Framework

Agency: Health Canada (HC)

HC released the Consumer Health Products Framework in November 2014. A 90-day consultation was followed by a series of webinars in January 2015, one of which included U.S. regulators. Additional webinars were held for the cosmetics, non-prescription drug, natural health product, and disinfectant industries. HC plans to publish a summary of what was heard from stakeholders during the Framework consultations.

Veterinary Drugs

Agencies: Health Canada, U.S. Food and Drug Administration (FDA)

Both agencies are continuing work on ten simultaneous reviews, which include companion animal, fish, and other food-producing animal products. New candidate submissions are being evaluated as others are nearing completion.

Chemicals Management

Agencies: Environment and Climate Change Canada (ECCC), U.S. Environmental Protection Agency (EPA)

Multi-stakeholder Technical Working Groups were formed in April 2015 to support the Risk Assessment and Significant New Activity (SNAc)/Significant New Use Rule (SNUR) initiatives under the Chemicals Management work plan. Meetings were held in the Fall in Washington, D.C. to enable in-depth discussion on work plan areas. Among the early results:

- Risk Assessment working group - the completion of a scoping exercise for a number of common forward priority substances as part of five case studies. This work included identifying areas of focus between jurisdictions for potential alignment which will later be used in the development of an Assessment Collaboration Framework.
- SNAc/SNUR working group - identification of opportunities for alignment and collaboration, including enhanced Canada-U.S. engagement, and the development of joint guidance materials to support compliance with SNAcs and SNURs. In addition, two stakeholder roundtable exercises were held to develop information on supply chain compliance challenges in Canada and the U.S., and to compile information on existing best practices for industry and government to facilitate supply chain communication on SNAc and SNUR requirements.

For further information, please contact rcc-ccr_substances@ec.gc.ca.

Engine and Vehicle Emissions

Agencies: Environment and Climate Change Canada

On July 29, 2015, ECCC published final amendments to the On-Road Vehicle and Engine Emission Regulations and the Sulphur in Gasoline Regulations in the Canada Gazette, Part II. The regulations will further limit emissions of smog-forming air pollutants from new cars, light trucks and certain heavy-duty vehicles (such as delivery vans) and reduce the allowable sulphur content of gasoline, in alignment with the EPA's "Tier 3" vehicle and fuel standards. The more stringent emission standards apply to 2017 and later model year vehicles and the lower sulphur limits take effect beginning in the 2017 calendar year.

The regulations are expected to result in air quality improvements in Canada and deliver significant health and environmental benefits to Canadians. Over the 2015-2030 period, the amendments to the two Regulations are expected to result in cumulative health and environmental benefits of \$7.5 billion, cumulative fuel and vehicle related costs of \$2.7 billion and net benefits for Canadians of \$4.8 billion (representing benefit-to-cost ratio of almost 3:1). Given the integrated nature of the North American economy, aligned Canada–United States Tier 3 vehicle and fuel standards are important to support the competitiveness of the Canadian automotive and fuel refining sectors. Alignment also provides Canadian companies with long-term regulatory certainty, helps with product planning and refinery updates, and minimizes administrative and compliance burden.

Workplace Chemicals

Agencies: Health Canada (HC), U.S. Occupational Safety and Health Administration (OSHA)

HC continues to engage stakeholders in various fora to communicate requirements of the *Hazardous Products Regulations* (HPRs), published in February 2015. HC requested input on priority areas of the development of technical guidance on HPR requirements. Furthermore, HC released guidance to stakeholders, with support from the OSHA on ingredient disclosure requirements on Safety Data Sheets and protection of Confidential Business Information, with a particular focus on guidance on ingredient concentrations and concentration ranges. This guidance noted that Canada and the U.S. are aligned on ingredient disclosure requirements. A Canada-U.S. working group is in place for ongoing technical discussions related to guidance and coordination of Globally Harmonized System of Classification and Labelling of Chemicals (GHS) implementation issues.

Discussions with OSHA were held in preparation for the 30th Session of the United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, in Geneva, Switzerland in December 2015. The Session involved experts from various countries discussing GHS implementation issues, including classification criteria, hazard communication and the development of guidance. HC participated in a public meeting with stakeholders, hosted by OSHA, where input was solicited on the working papers and informal documents published on the UN website.

HC and OSHA continue to collaborate on alignment of hazard classification and communication requirements for workplace chemicals, as per RCC work plan activities, without reducing the level of safety or protection to workers. HC hosted a stakeholder meeting in early

December and in collaboration with U.S. OSHA, provided an update on RCC activities and requested stakeholder feedback on the RCC Work Plan. A face-to-face meeting between HC and OSHA to discuss GHS implementation occurred in January 2016.

Plant / Animal Health, Meat Inspection and Certification

Agencies: Canadian Food Inspection Agency (CFIA), U.S. Department of Agriculture (USDA)

In June 2015, both agencies hosted a teleconference with more than 170 stakeholders to introduce the recently-released work plans for Animal Health, Plant Health and Meat Inspection and Certification. Officials also provided an overview of their new regulatory partnership and the importance of stakeholders in contributing to this work. A subsequent session took place in January 2016 to report on progress made to work plans since the meeting in June, and reinforced the need for stakeholders to identify areas of strategic importance in the near, medium and long term to support greater regulatory cooperation.

Motor Vehicles

Agency: Transport Canada (TC)

An amendment to the Motor Vehicle Safety Regulations was published in *Canada Gazette*, Part II, in June 2015. This amendment aligns Canada Motor Vehicle Safety Standard (CMVSS) 122 – Motorcycle Brake Systems to the new U.S. safety standard. Maintaining alignment has the benefit of updating and improving the current Canadian baseline performance requirements, and relieving manufacturers of any unnecessary burden that could result from misaligned requirements.

Connected Vehicles

Agencies: Transport Canada (TC), U.S. Department of Transportation (USDOT)

At the Intelligent Transportation Systems (ITS) Canada 18th [Annual Conference and General Meeting](#) in May 2015, TC officials presented the [Connected Vehicles Work-Plan](#). USDOT [ITS Joint Program Office](#) officials also presented their work on CVs, including the Connected Vehicle Reference Implementation Architecture (CVRIA), CV Affiliated Test Beds, CV Safety Pilot Program and the CV Pilot Deployments. TC, USDOT, and ITS Canada also co-hosted a technical workshop on the CVRIA, which is a graphical representation of how devices intercommunicate and how data flows between different systems and users, and is used by engineers, programmers, researchers and others to develop CV components. Both of these sessions fulfilled key RCC commitments by TC and USDOT to jointly engage stakeholders on bi-national and related international CV issues, and to undertake activities to harmonize the CVRIA into Canada-U.S. National ITS architectures.

Rail Cars

Agencies: Transport Canada, U.S. Department of Transportation (USDOT)

Both agencies have been working to bring forward a harmonized flammable liquid tank car standard, including retrofit and timeline requirements for older tank cars. This initiative will enable the free flow of flammable liquids across our shared border, providing Canadian producers and refiners access to valuable markets while improving public safety during the

transport of dangerous goods by rail. Regulations for this initiative (Tank Cars 117) were published in the *Canada Gazette*, Part II in May 2015.

Natural Gas Vehicles

Agencies: Natural Resources Canada (NRCan), U.S. Department of Energy (USDOE)

The year-one work plan, published in May 2015, outlined three broad areas of collaboration between both agencies to facilitate the deployment of natural gas vehicles and refuelling infrastructure: revising existing codes, developing new binational standards, and working with regulatory bodies across multiple jurisdictions. The development of the first two binational standards for liquefied natural gas refuelling nozzles and vehicle storage containers is well underway, and is anticipated for publication in Spring 2016.

The scope and activities of an existing Canadian natural gas vehicle technical advisory group have been broadened to include U.S. stakeholders and the USDOE. This group, co-chaired by NRCan, provides a mechanism for ongoing stakeholder consultation to ensure that current RCC activities are aligned with their priorities, while identifying possible issues to be included in subsequent work plans. Discussions were also held in October 2015 during the CSA Group US Committee week in Cleveland, Ohio, where additional priority areas for code development were identified.

Personal Flotation Devices Standards

Agencies: Transport Canada, U.S. Coast Guard (USCG)

The first joint Canada-U.S. national standards for personal flotation devices were published by Underwriters Laboratories on December 31, 2015 and were adopted simultaneously by Canada and the U.S. The publication of these standards is a ground-breaking achievement as Canada and the U.S. used a single consensus body, comprised of key Canadian and American stakeholders, international participants and representatives from the U.S. Coast Guard and Transport Canada, to publish a single document for use in both countries. The adoption of these ISO-based standards marks the first time that consumers can purchase a product for use in both Canada and the U.S. The simultaneous adoption of the joint standard eliminates duplication in testing, allows for greater innovation in production, and enables market access while maintaining high quality standards.

Nuclear Safety

Agencies: Canadian Nuclear Safety Commission (CNSC), U.S. Nuclear Regulatory Commission (USNRC), U.S. Department of Transportation (USDOT)

Highly enriched uranyl nitrate liquid (HEUNL) is a by-product of the manufacture of life-saving medical isotopes at Canadian Nuclear Laboratories' [Chalk River Laboratories](#). In March 2012, [Canada expanded its commitment to return highly enriched uranium \(HEU\) to the U.S.](#) to include material in liquid form, such as HEUNL, as part of a broad international effort to consolidate HEU inventories in fewer locations around the world. This commitment promotes non-proliferation by removing weapons-grade material from Canada and eliminates a nuclear liability for future generations.

The design of the package intended for the transport of HEUNL from Canada to the U.S. required certification by both countries. Although the certifications were performed independently, both countries used common requirements to review the application, and information was shared between CNSC, USNRC and USDOT to ensure the most effective and efficient review. By July 2015 all three agencies had issued certificates.

For more information on HEUNL transport package design certification, please visit the [CNSC web site](#).

RCC SECRETARIAT NEWS

RCC Welcomes Les Linklater as Canada's new RCC Co-Chair

As of July 20th, Les Linklater, the Government of Canada's Deputy Secretary to the Cabinet (Operations), has now assumed the role as Canada's new RCC co-Chair.

RCC Welcomes Greg Wolff as Canada's new RCC Executive Director

As of November 16th, Greg Wolff has now assumed the role of Canada's new RCC Executive Director.

TO STAY CONNECTED OR FOR MORE INFORMATION

The RCC website has moved to <http://pco-bcp.gc.ca/rcc>.

Please refer to the new website for general information, including departmental regulatory partnership statements and work plans or send us an email at rcc-ccr@pco-bcp.gc.ca. You can also visit <http://trade.gov/rcc> to access information from the U.S. secretariat.

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