

Canada-United States Regulatory Cooperation Council 2018 Stakeholder Forum

Executive Summary

The Canada-United States Regulatory Cooperation Council (RCC) 2018 Stakeholder Forum was held December 4–5, 2018, in Washington, D.C. It was a successful 1.5-day event that brought together approximately 300 stakeholders and regulators. The event consisted of a plenary session and four sets of breakout sessions.

Canada's Ambassador to the United States, David MacNaughton, gave introductory remarks followed by keynote addresses by Mick Mulvaney, Director of the U.S. Office of Management and Budget, and Scott Brison, President of the Treasury Board of Canada. Key themes of the opening speeches included the importance of the Canada-United States relationship and the role of regulatory cooperation in reducing regulatory burden to stimulate the economy while still maintaining high standards and protections for health, safety, and the environment.

The keynote addresses were followed by an industry panel to discuss RCC successes—past, present, and future. Panelists highlighted successes of the RCC, such as the Sunscreen Pilot, standards for a new class of rail tank car for flammable liquids, motor vehicle safety, and chemicals management. It was noted that a key achievement of the RCC is that it transcends administrations.

As regulators and stakeholders began the first set of breakout sessions, the RCC Council held a council meeting. The Council was co-chaired by Peter Wallace, Secretary of the Treasury Board of Canada, and Neomi Rao, Administrator of the U.S. Office of Information and Regulatory Affairs. They were joined by Michael Keenan, Deputy Minister of Transport Canada, and Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency.

Twelve breakout sessions were held on the following topics: medical devices; alternative fuel use in transportation; aviation and unmanned aircraft systems; crop protection; vehicle safety and connected vehicles; consumer product safety; rail safety; chemicals management and workplace chemicals; small modular reactors; transportation of dangerous goods; animal health, veterinary drugs, and meat inspection; and border trade data systems. All sessions began with an overview by regulators on regulatory cooperation activities and work plans, followed by questions and answers.

Throughout the event, stakeholders expressed broad support for the RCC and, in many cases, applauded efforts by regulators to work together and reduce unnecessary duplication in our regulatory systems. Regulatory cooperation for emerging technologies was also a theme stakeholders raised across subject areas, which many regulators are already discussing bilaterally. Other key themes raised by stakeholders included the use of international

standards, the increased use of electronic tools for regulatory requirements, and increased work-sharing and mutual recognition where possible.

Regulators and stakeholders re-convened for end of day remarks and a debrief of the Council meeting by Secretary Wallace and Dominic Mancini, Deputy Administrator of the U.S. Office of Information and Regulatory Affairs.

Overview

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Canada's Ambassador to the United States, David MacNaughton, gave introductory remarks followed by keynote addresses by Mick Mulvaney, Director of the U.S. Office of Management and Budget, and Scott Brison, President of the Treasury Board of Canada. Key themes of the opening speeches included the importance of the Canada-United States relationship and the role of regulatory cooperation in reducing regulatory burden to stimulate the economy while still maintaining high standards and protections for health, safety, and the environment.

The keynote addresses were followed by an industry panel to discuss RCC successes—past, present, and future. The panel was moderated by Susan Dudley, Director of the George Washington University Regulatory Studies Center. The panelists were: Michael Fitzpatrick (Head of Regulatory Advocacy, General Electric Global Law and Policy), Mark Nantais (President, Canadian Vehicle Manufacturers' Association), Kristin Willemsen, (Director, Scientific and Regulatory Affairs, Consumer Health Products Canada), and Michael Walls (Vice President of Regulatory and Technical Affairs, American Chemistry Council). Panelists highlighted successes of the RCC, such as the Sunscreen Pilot, standards for a new class of rail tank car for flammable liquids, motor vehicle safety, and chemicals management. It was noted that a key success of the RCC is that it transcends administrations. One panelist also noted that in some sectors, the biggest barrier to trade is regulatory misalignment. For emerging technologies, such as unmanned aircraft systems, automated and connected vehicles, and artificial intelligence, panelists cautioned governments not to regulate too early, but rather to watch industry developments closely and work to regulate on an as-needed basis. The panelists also shared advice and lessons learned: be persistent, back up good ideas with evidence, and have manageable work plans. They also noted the importance of government responses to industry proposals, even if the responses are negative.

As regulators and stakeholders began the first set of breakout sessions, the RCC Council held a council meeting. The Council was co-chaired by Peter Wallace, Secretary of the Treasury Board of Canada Secretariat, and Neomi Rao, Administrator of the U.S. Office of Information and Regulatory Affairs. Secretary Wallace and Administrator Rao also invited colleagues Michael Keenan, Deputy Minister of Transport Canada, and Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency, to join them in the Council.

Regulators and stakeholders re-convened at the end of the day for a debrief of the council meeting by Secretary Wallace and Dominic Mancini, Deputy Administrator of the U.S. Office of Information and Regulatory Affairs. The Council discussion included key points of interest:

- Emerging technology, specifically connected vehicles;
- Cybersecurity protocols and the collection of information and data, which are important to understand as North America moves into the expanded use of connected and automated vehicles; and,
- Leveraging paperwork reduction to develop more efficient ways to collect electronic information.

The Council was interested in hearing about the discussions in the breakout sessions, as well as ideas for future areas of cooperation. These comments could also be submitted to the Request for Information that the U.S. Office of Information and Regulatory Affairs had recently published.

Twelve breakout sessions were held over the day and a half. All sessions began with an overview by regulators on regulatory cooperation activities and work plans, followed by a question and answer period. Throughout the event, stakeholders expressed broad support for the RCC and, in many cases, applauded efforts by regulators to work together and reduce unnecessary duplication in our regulatory systems. Regulatory cooperation for emerging technologies was also a theme stakeholders raised across subject areas, which many regulators are already discussing bilaterally. Other key themes raised by stakeholders included: use of international standards, increased use of electronic tools for regulatory requirements, and increased work-sharing and mutual recognition where possible.

The topics of the breakout sessions were:

- [Medical devices](#);
- [Alternative fuel use in transportation](#);
- [Aviation and unmanned aircraft systems](#);
- [Crop protection](#);
- [Vehicle safety and connected vehicles](#);
- [Consumer product safety](#);
- [Rail safety](#);
- [Chemicals management and workplace chemicals](#);
- [Small modular reactors](#);
- [Transportation of dangerous goods](#);
- [Animal health, veterinary drugs, and meat inspection](#); and
- [Border trade data systems](#).

For a summary of a specific breakout session, click on the links above.

Medical Devices

The U.S. Food and Drug Administration (FDA) and Health Canada are working together on pre- and post-market regulatory convergence topics, including in particular, through the International Medical Devices Regulators Forum (IMDRF). The IMDRF aims to accelerate international medical device regulatory harmonization and convergence for regulators and stakeholders worldwide. Past and present work items include Medical Device Single Audit Program (MDSAP), Table of Contents format, cybersecurity (FDA and Health Canada to co-chair), and the development of a Medical Device Single Review Program (MDSRP). As of January 2019, MDSAP is mandatory in Canada. Health Canada and the FDA expressed that pre-market burden could be reduced for both regulators and industry through the MDSRP, allowing for access to multiple jurisdictions following a single review. FDA and Health Canada also reported on their collaboration on digital health to align regulatory requirements. Health Canada is developing guidance documents on 3D printing, cybersecurity, and software as a medical device.

Stakeholders expressed support for continuing the regulatory cooperation between FDA and Health Canada on medical devices. Stakeholders inquired about how best to involve other countries and how the RCC interplays with the IMDRF. FDA and Health Canada explained that the relationship between the RCC and the IMDRF flows both ways, with the RCC providing a venue to pilot projects from the IMDRF.

Stakeholders expressed interest in collaboration between the two regulators on novel approaches and emerging technologies (e.g., point-of-care medical devices) and whether opportunities for work-sharing or mutual recognition exist. The role of standards was also raised, as was the possibility of alignment with FDA's standards program.

Stakeholders also expressed concern about the review of medical devices, which has been in the media recently in Canada. Health Canada noted that the Minister of Health set out a path forward, and that it will not affect the RCC's work.

Alternative Fuel Use in Transportation

The U.S. Department of Energy (DOE) and Natural Resources Canada (NRCan) each spoke about efforts to date, and possibilities looking forward. They highlighted that this initiative builds on the more than 20 years of collaboration between the two departments on alternative fuel use in transportation.

The focus of this RCC initiative is to align codes and standards for alternative fueled vehicles and refueling infrastructure. These efforts ensure that consumers and fleets who choose to operate alternative fueled vehicles can be confident that the technologies are similar regardless of which geographical region they travel throughout the United States and Canada, contributing to energy security, reducing fuel costs, and reducing emissions. These efforts also ensure businesses can design products to one set of specifications for both the U.S. and Canadian markets, thereby reducing costs and contributing to their competitiveness.

The scope of the initiative originally only included natural gas use in on-road transportation, however, in 2016 this scope was broadened to include all alternative fuels (e.g., electric vehicles, hydrogen, natural gas, and propane), as well as emerging uses like marine and rail applications.

It is important to note that neither DOE nor NRCan are the regulators when it comes to alternative fuel use in transportation. This is regulated at the state, provincial, or territorial level.

Stakeholders expressed interest in adding other fuels into future RCC work plans and noted that misalignment between federal, state, or provincial regulations is impeding innovation in a highly evolving sector of the transportation industry. Specific topics raised by stakeholders included bringing down the cost of hydrogen fuel cells and propane. Stakeholders indicated that governments should better align regulatory efforts to empower innovation and economic growth. DOE and NRCan continue to work on this Initiative, as well as identifying and prioritizing the next areas of focus.

Aviation and Unmanned Aircraft Systems

The U.S. Department of Transportation's (DOT) Federal Aviation Administration (FAA) and Transport Canada (TC) then each spoke briefly to their ongoing collaboration and positive working relationships in the area of aviation safety and unmanned aerial vehicles. Following these remarks stakeholders had the opportunity to provide comments and ask questions of the regulators.

Stakeholders asked about the extent of Canada's engagement in the FAA Integration Pilot Program (IPP). TC indicated that they have visited the United States to learn about the program from the FAA and are keen to gather more information.

Stakeholders expressed interest around airspace management—specifically around the potential challenge of aligning rules because of differences in air traffic management between the United States and Canada. Both TC and the FAA indicated that they do not anticipate this being a problem.

Similarly, stakeholders asked about potential difficulties of the United States and Canada aligning their final rules, given their two very different geographies. TC acknowledged that telecommunications for command and control could be a challenge, especially in the north where there may be infrastructure limitations. However, this would not necessarily change how we regulate.

Stakeholders raised the importance of reciprocity for drone licencing across the United States and Canada. TC indicated that reciprocity is essential, especially for larger drones and for operations beyond visual line of sight. Common certification standards would be helpful, but this then raises questions around assessing certification and product testing.

Stakeholders raised the importance of communicating safety messaging to stakeholders. TC indicated that they have a user-friendly web site to answer these questions. DOT noted that a number of stakeholders have asked the agency to ramp up communications and outreach on safety messaging, similar to other countries that have innovative outreach methods (e.g., the United Kingdom and Canada). TC noted that there is a great diversity of stakeholders extending beyond entities interested in commercial and recreational use. There is a need for more apps and digital tools for users, as well as a need to work with manufacturers and retailers on safety messaging.

Crop Protection

The U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) and Health Canada's Pest Management Regulatory Agency (PMRA) provided an update on their pesticide program collaborations that fall under the RCC. The two agencies have a long history of cooperation and partnership and continue to work closely on many issues. The agencies highlighted their work on neonicotinoid pesticides, particularly in the area of risk assessment. On this topic, both countries review the science in similar ways. However, they noted they are not on the same timeline for reviewing submissions. EPA and PMRA are continuing to take a close look at their re-evaluation processes and are working with counterparts at the Organisation for Economic Co-operation and Development (OECD). For new active ingredients, it has become routine for industry to submit to both the United States and Canada concurrently, which has led to increased efficiencies for industry and governments. The agencies are also continuing to work on developing new integrated approaches to testing and assessment. With respect to aligning residue trial requirements, EPA and PMRA harmonized trial requirements in 2017 and 2018. Residue trial requirements determine what levels of chemicals can remain on products and are a major aspect of the approval process. EPA and PMRA also recently worked on the development of joint information technology solutions and continue to look at ways to more efficiently share information between regulators.

EPA and PMRA expressed interest in hearing from stakeholders about what their priorities for the RCC should be going forward. They heard and understood the importance of joint reviews, and have committed to continuing with their collaborative work. They also noted that maximum residue limits (MRLs) for joint reviews are relatively aligned. They have also heard from stakeholders that they would like to see more alignment on biocides.

Stakeholders had a number of suggestions for continuing U.S.-Canada cooperation on pesticides. They expressed a clear desire for aligned timelines and outcomes. EPA and PMRA indicated that their legislative frameworks require different assessments, which can lead to different outcomes. Regulators also noted that during the public comment process different information is provided to each country, which can lead to different timelines even if the risk assessments were posted for public comment at the same time.

One stakeholder suggested that Canada mirror the EPA's bio-pesticides program, which provides bio-pesticides with a shorter and less costly path to registration. Another noted that they would like to see further cooperation in the area of biocides, in particular joint reviews and for Canada to accept the reviews of the United States. Reliance on the Asia-Pacific Economic Cooperation process and MRL approach was also raised by stakeholders.

Stakeholders also raised emerging technology (e.g., drones). EPA and PMRA noted that they have been discussing this with each other and industry.

Vehicle Safety and Connected Vehicles

The U.S. Department of Transportation (DOT) and Transport Canada (TC) provided brief status updates on the RCC work plan for connected vehicles (CVs) and motor vehicle safety that were presented at both the 2016 and 2014 RCC stakeholder meetings. The parties reinforced their close working relationships and the intent to continue working on themes, including cyber security, spectrum analysis, infrastructure, regulatory development, joint research testing, new regulations, and existing regulation. With respect to CVs, both parties highlighted the need to align codes and standards regarding transportation architecture in order to ensure connected vehicles can be deployed and be interoperable in both countries. Regarding motor vehicle safety, side impact protection, ejection mitigation, and electronic stability control for transport trucks and buses were high priority areas where Canada aligned with the United States.

Stakeholders asked whether DOT and TC could pool and release data, indicating that there could be very real benefits to sharing information in this way. TC indicated that there is a great deal of collaboration on safety with respect to hydrogen and electric vehicles. At the same time, TC is in the process of taking a fresh look at how they post research.

Stakeholders also raised concerns about the condition of trucks when they are used in platooning, especially with respect to their brakes.

Stakeholders asked about alignment of requirements for rear impact guards on truck trailers. Stakeholders indicated that a few years ago the United States was looking to institute a requirement for these, but it would not have aligned with rules in Canada.

With respect to the safety of automated vehicles (AVs), stakeholders inquired about the decision-making process when programming AVs. The suggestion was made to implement legislation to protect companies from liability in case of injury from an AV. TC indicated that they have developed safety assessment guidelines that will soon be released.

Stakeholders also suggested that although AVs and CVs are developing in parallel, they are still separate technologies that should be addressed in separate RCC work plans.

Stakeholders asked about the status of Canadian requirements for automatic headlights in automobiles. TC indicated that this is not a regulatory requirement, but one allowable method of complying with recently updated lighting requirements (CMVSS 108) that seek to mitigate the occurrence of vehicles travelling at night or in low ambient light conditions without their full running lights operating. Stakeholders also advocated for greater collaboration and synchronization between DOT's National Highway Traffic Safety Administration (NHTSA) and TC on lighting issues. NHTSA appears to be considering updating its lighting regulation (FMVSS 108)

to allow certain advanced lighting technologies that TC has allowed when CMVSS 108 was updated.

Consumer Product Safety

Health Canada highlighted that despite the absence of a RCC work plan on consumer product safety, it works closely with the U.S. Consumer Product Safety Commission (CPSC) to monitor risk and discuss approaches to a number of areas of consumer products, including emerging areas in the global online marketplace.

Health Canada outlined the points in the process where Health Canada and the CPSC cooperate, including in the areas of information sharing; surveillance and triage of products; risk assessments; and laboratory work. Since 2009, the United States and Canada have jointly issued 600 product recalls, which demonstrates the level of engagement and cooperation that is ongoing.

The CPSC was unable to attend the breakout session due to the National Day of Mourning.

Given the breadth of topics captured under the consumer product safety theme, there were a number of disparate questions from stakeholders. There was particular interest in the Internet of Things and the ways that “smart” products can be integrated into the marketplace safely. There were questions about international standards, the number of consumer product safety incidents involving these products, and how the United States and Canada can collaborate more in the global space to share lessons learned and best practices. Stakeholders also raised the importance of unique identifiers in the global market, especially in relation to recalls and ensuring that recalls capture the right products in as many markets as possible. Stakeholders also raised a number of questions regarding the approaches to products affecting the health and safety of children (e.g., window coverings, children’s pyjamas, and car seats) and how the approaches in the United States and Canada differ despite regulatory cooperation in other spheres.

Rail Safety

The U.S. Department of Transportation's Federal Railway Administration (FRA) and Transport Canada (TC) reinforced that the collaboration between them is ongoing and positive. FRA noted that there is potential for amendments to U.S. brake system standards to align with Canada. TC spoke to the importance of in-cab recordings for safety, but also for accident reconstruction. Draft regulations to this effect are being developed in Canada for summer 2019, with final regulations expected in spring 2020. For fatigue management, TC published a Notice of Intent in November 2017 and intends to make changes to the regulatory framework with respect to time away and rest times for rail operators.

Stakeholders inquired about the status of dialogues on emerging technologies (e.g., hyper loop). FRA and TC acknowledged that discussions on new technologies are ongoing. Stakeholders also asked about possible alignment on positive train control, so that U.S. and Canadian requirements are inter-operable. FRA and TC stated that there are ongoing dialogues on positive train controls, with Canada slightly behind the United States. A third area of interest was the potential for cooperation in the area of intermodal transport. Although intermodal transport has not been a focus of cooperation to date, currently some joint inspections can be done in intermodal areas.

Chemicals Management and Workplace Chemicals

Workplace Chemicals

The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) and Health Canada provided an update on the workplace chemicals work plan under the RCC. Both countries are active in engaging stakeholders. While they have always enjoyed a positive relationship, the RCC provided a platform for increased collaboration. For example, OSHA and Health Canada successfully implemented the Globally Harmonized System of Classification and Labelling (GHS) and continue to align on their technical interpretation of the GHS, working together on common positions and then taking them to the global level. Both are also seeking alignment in updating the seventh edition of the GHS. The United States and Canada meet regularly on this issue and are working towards joint guidance documents in the following areas: Comparison of Labelling Requirements for Hazardous Products, Labelling Pictogram for Hazards Not Otherwise Classified, and Regulatory Processes Comparison Document. These will be shared with stakeholders shortly.

OSHA and Health Canada also announced that their MOU concerning health and safety in the workplace with respect to the development and implementation of the GHS has been renewed.

Moving forward, OSHA and Health Canada will continue to collaborate on implementing updates to the GHS in their respective jurisdictions. For the next round of RCC work plans, proposed work includes:

- Continued development of joint guidance materials;
- Coordination of common positions and participation in international discussions on the GHS; and
- Maintaining alignment between the two countries as GHS updates are implemented.

Chemicals Management

The U.S. Environmental Protection Agency (EPA), Environment and Climate Change Canada, and Health Canada provided an update on the work plan for chemicals management, which consists of two work streams: risk assessment, and Significant New Activity (SNAC) provisions and Significant New Use Rules (SNURs). Under the risk assessment work stream, Health Canada and EPA conducted a comparative analysis of risk assessment frameworks, collaborated on chemicals that were of common priority, and developed an assessment collaboration framework with the goal of increasing alignment. This framework, developed between 2016 and 2018, will enable enhanced alignment on risk assessment of chemicals, including identification of risk assessment priorities, information gathering and sharing, risk assessment

methodologies, work sharing, and joint assessments. The framework is now being operationalized through a rolling work plan.

Under the SNAc and SNURs work stream, regulators held technical working group meetings to help develop a comparative analysis of jurisdictional, regulatory, policy, and program aspects. Stakeholder interviews were also conducted to better understand the differences between jurisdictions and the challenges faced by stakeholders. This work highlighted the need for continued collaboration to:

- Facilitate and enhance communication between regulators;
- Develop materials and approaches to improve understanding; and
- Improve supply chain communication.

Key Themes Raised by Stakeholders

Stakeholders expressed support for the ongoing work on chemicals management and workplace chemicals.

Workplace Chemicals

One stakeholder asked about updating to GHS revision 8, which is currently being finalized. Health Canada noted that their projected implementation of revision 7 was in March, and that they did not want it further delayed. Another issue raised was more protections for workers using antimicrobials in the United States.

Chemicals Management

Stakeholders indicated a desire to see a work plan on chemicals risk management. Regulators noted that Canada and the United States are at different stages on this issue.

Stakeholders highlighted misalignment in confidential business information (CBI) processes as an impediment, particularly Canada's claims process, which has fees. A member of the fragrance industry noted that this is particularly onerous for them, given that fragrances contain many chemicals. Health Canada noted that CBI is a major impediment to them working more collaboratively with the United States and will be considering the comments heard. They also noted that they are currently consulting on the form for the new substances program, which would include a question as to whether they could share the CBI with the United States and with the European Chemicals Agency.

Other issues raised include chemical nomenclature and alternatives to animal testing.

Small Modular Reactors

The Canadian Nuclear Safety Commission (CNSC) and the U.S. Nuclear Regulatory Commission (NRC) presented to a small group of stakeholders about the current regulatory environment governing Small Modular Reactors (SMRs) and the path forward.

The CNSC regulates all nuclear activities, including mining, transportation, dosimetry, waste, and processing. The NRC is an independent agency that licenses the use of radioactive materials in the United States, including by commercial power reactors and in medical applications.

SMRs are different from water-based Generation II and III reactors with respect to the technologies and coolant used, as well as the security by design. There are also new approaches to deploying SMRs with respect to ownership, plant operation (i.e., staffing or autonomous operation), and factory-fuelled transportable reactors. A stakeholder-led Canadian SMR roadmap was released in November 2018, and the Government of Canada is currently reviewing its findings and recommendations.

Canadian Nuclear Laboratories (CNL) are engaged with SMR vendors with the goal to host an SMR on a CNL site by 2026. They are working to better understand the market demand for SMRs, including vendor, utility, and provincial government interest. Vendors are currently engaged with CNSC to present designs for review in order to better understand the Canadian regulations and licensing process. There are currently 10 vendors design reviews in progress.

The CNSC conducted a consultation with stakeholders regarding the growing public interest in SMRs and the potential need for changes to the nuclear regulatory framework. In 2017, they published a “What we heard” report that stated the next steps to providing clarity to SMR regulations are potential amendments to the Nuclear Security Regulations, providing clarity on grade approach to vendor reviews, and providing clarity on licensing SMRs.

The CNSC is currently cooperating with other countries in benchmarking and information exchange with other countries in similar situations. This includes reaching out to the International Atomic Energy Agency (IAEA), the Nuclear Energy Agency (NEA) working groups on SMR at the OECD, the Multinational Design Evaluation Program, and the group on the Safety of Advanced Reactors. Bilateral agreements with the U.S. Department of Energy (DOE) also led to molten salt reactor training and information sharing on gas cooled reactors.

The presentation outlined the process for each of these next steps and concluded that the current regulatory framework is adequate for licensing advanced technology. CNSC will continue to outline its approach and prioritization efforts to provide regulatory clarity with leadership from CNSC senior management.

Stakeholders asked what the current acceptance of SMRs and nuclear power in general is like in new jurisdictions and wondered if it will be difficult to sell citizens on the potential for SMRs.

CNSC said there are regions across Canada that are interested in the technology but are waiting for vendor designs to mature before committing.

Stakeholders asked if they are allowed to approach the U.S. government to propose designs that may be outside the current regulations. The United States indicated that designs need to be based on regulations, but the NRC regulations provide some flexibility with respect to acceptable alternatives. The U.S. process does not incorporate a vendor design review option with the same flexibility as Canada, because the NRC approves standard design certifications that licensees can adopt, rather than case-by-case project proposals. The U.S. and Canadian regulatory approaches to nuclear power differ but are typically complimentary. The CNSC and the NRC can and do share expertise gained through their respective experiences working with different applicants.

A stakeholder asked if there has been any consideration of incorporating Canada, the United States and Mexico into a Pan North American nuclear regulatory framework. Officials noted there have been conversations with Mexico in the past, but no serious discussions for the last five to seven years.

Transportation of Dangerous Goods

The U.S. Department of Transportation (DOT) reinforced the ongoing and strong links between DOT and Transport Canada (TC) (e.g., reciprocity for inspections and repairs for tank cars and mutual recognition of special permits and approvals). TC reinforced the longstanding collaboration with DOT and the U.S. Pipeline and Hazardous Materials Safety Administration (PHMSA), such as through the harmonisation of cylinder requirements. TC also spoke to cooperation outside the RCC, for example through standard development committees for tank cars. Both the Treasury Board of Canada Secretariat (TBS) and DOT indicated that they were looking forward to hearing from stakeholders about challenges to their industry, what federal regulators have done well, and what could be improved. TC also hoped to use this session to check back with stakeholders on some of the messages they have heard through recent consultations.

Stakeholders asked about the requirement to re-test small packages after five years, as well as the period of testing for medium-sized packages (e.g., intermediate bulk containers). TC committed to looking into these requirements and responding in the days following the session. Stakeholders suggested the United States should consider changing the timeframe of retesting single packaging from at least every 12 months to five years.

Stakeholders noted the potential for distributed ledger technology (e.g., blockchain) to be used for secure transportation through the use of smart contracts. In response, TC indicated that blockchain is important as part of their five-year policy plan, but it is not yet known whether this could be in the context of TDG.

Stakeholders asked whether Canada has current research on the potential use of electronic shipping papers. TC indicated that they are looking to collaborate with DOT on this research. TC is also looking to collaborate with the PHMSA to study innovative ways to replace paper documents with electronic documents, which could be accessible to emergency responders and allow for an equivalent level of safety. With respect to innovation, TC is also looking to explore innovative approaches to electronic shipping papers, special permits and exemptions, display packaging, and labels and placards.

Stakeholders noted that older tank cars used for flammable liquids (e.g., crude oil) are being phased out more quickly in Canada as compared to the United States and asked whether these accelerated timelines will apply for tank cars for other flammable liquids. TC acknowledged that the phase-out of DOT 111 cars is happening faster in Canada, but that the phase-out dates of cars used for ethanol are aligned with the U.S. dates.

Two stakeholders asked whether Canada has an incident reporting form similar to the PHMSA. TC responded that Canada has similar incident reporting requirements as PHMSA. TC provides a voluntary 30-day incident follow-up form to assist stakeholders in meeting their incident reporting requirements, although use of the form is voluntary. TC currently does not have an electronic online reporting system, but Canada is looking to improve this.

Stakeholders expressed interest in knowing more about TC's upcoming proposed regulations on training for the transportation of dangerous goods. TC indicated that they are currently developing a competency based training and assessment standard in partnership with the Canadian General Standards Board.

Stakeholders also asked for more information about TC'S interpretation of, and limitations on, "re-shipping" (i.e., when a company that receives dangerous goods is required to produce a new shipping document before distributing these dangerous goods).

Animal Health, Veterinary Drugs, and Meat Inspection

Animal Health

The Canadian Food Inspection Agency (CFIA) and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) provided an overview of their recent work on animal health.

The work on zoning continues to move forward, and the bilateral Zoning Arrangement and the accompanying Guidance Framework has been revised based on lessons learned during initial implementation and via stakeholder comments. In August 2018, the Arrangement was updated, revised, and re-signed by both countries. A joint proposed agreement has been developed to allow the transit of live animals between countries in case of emergency. This proposal is currently under legal review, but both regulators are hopeful that it can be concluded in the near future. Development and implementation of electronic certification continues, as do pilot projects which have significantly reduced the time required to receive and exchange certificates.

Stakeholders expressed concern about African Swine Fever and asked what regulators were doing. Both regulators responded that the mitigations currently in place are strong and that they are working together and with Mexico on a North American approach. Other issues raised by stakeholders included zoning, joint surveillance, and traceability. One stakeholder wanted to better understand what is being done in terms of harmonizing certification.

Veterinary Drugs

Veterinary drugs have been in the RCC since its first phase, with the goal of simultaneous reviews, leading to simultaneous access. Since 2012, Health Canada and the U.S. Food and Drug Administration (FDA) have completed 10 simultaneous reviews (6 for companion animals, 4 for food animals). Another 18 simultaneous reviews are underway (11 for companion animals, 7 for food animals). Regulators are also looking at internal mechanisms to make sure that submissions are processed and handled in a timely manner and are engaging drug companies to make sure that these mechanisms are working for them. Enabling the submission of applications to both regulators through a single electronic portal is also being explored. In response to stakeholder suggestions for aligning maximum residue limits (MRLs), dosages, and withdrawal times, Health Canada and the FDA noted that veterinary drugs approved through simultaneous reviews have similar conditions of use given the collaborative scientific review. Health Canada also noted that in May 2018 they made regulatory changes regarding the quality and oversight on the importation of active pharmaceutical ingredients for veterinary use, achieving greater international alignment.

Stakeholders expressed strong support for the existing work on simultaneous reviews. Stakeholders also noted that the United States is in the early stage of regulating gene-editing for food animals and inquired as to the status in Canada. Suggestions for continued collaboration include environmental assessment, veterinary biologics, and joint templates. Stakeholders also suggested that they be given an opportunity to beta-test templates. Stakeholders would also like to see increased alignment on MRLs. Under the RCC, Health Canada and the FDA looked at data sets and found that MRL differences, where they exist, are small and do not result in trade issues for meat. Health Canada and the FDA also noted that there are other international bodies that work on the issue of MRLs and food safety.

Meat Inspection and Certification

CFIA and the USDA's Food Safety and Inspection Service (FSIS) provided a joint update highlighting their commitment to work together and ongoing collaboration to resolve day-to-day issues and exchange information on regulatory developments. There have been advancements in the equivalency of testing methodologies with future work looking at the possibility of harmonizing the validation process for laboratory methods to move away from a method-by-method review. The work done by industry alongside government on the export library was recognized with a commitment to reinvigorate that work and seek conclusion in the near future.

Stakeholder comments largely focussed around the issue of re-inspection and testing procedures at the border, with some stakeholders advocating for increased inspections of imported product and others arguing that it is duplicative and contradicts equivalency. There was a suggestion by stakeholders that they start small to remove this requirement.

Border Trade Data Systems

The presentation from the Canadian Border Services Agency (CBSA) highlighted the impact e-commerce is having on border processing. The volumes are increasing but mainly for items destined for individual consumers. Given the shift in the global online marketplace, CBSA and the U.S. Customs and Border Protection (CBP) are exploring ways to further innovate the data systems and the ways in which information is collected, including through the use of emerging technologies such as blockchain. CBSA and CBP both indicated that such technology will be implemented by the private sector, while the government becomes the facilitator. The goal is to reduce duplication of data and provide transparency into the authenticity of shipments, while making the technology interoperable. Conversations on how to further advance the data collection systems between Canada, the United States, and Mexico are ongoing. Alignment is also important at the state or provincial level to prevent duplication and ensure the safety of incoming goods and the safety of personal information collected.

While stakeholders recognize the importance of technology, such as blockchain, for the future of border trade, there are ongoing challenges with the current systems, which are neither fully electronic nor fully integrated across North America. Stakeholders indicated that Canada and the United States should explore international models where in-land customs processes and pre-clearance agreements help ease congestion at the border. Stakeholders also indicated that initiatives such as the Global Trade Identification Number could assist in preparing for the future introduction of blockchain technology as well.