



International Centre for Trade  
and Sustainable Development

# Regulator Considerations: Leveraging Opportunities through Regulatory Cooperation

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June 2017

Think Piece



[rtaexchange.org](http://rtaexchange.org)

# Acknowledgements

## Published by

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Publisher and Chief Executive: Ricardo Meléndez-Ortiz

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1300 New York Avenue, N.W., Washington, D.C., 20577, USA  
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## Acknowledgements

This paper has been produced under the RTA Exchange, jointly implemented by the International Centre for Trade and Sustainable Development (ICTSD) and the Inter-American Development Bank (IDB). For more information on the RTA Exchange, please visit [www.rtaexchange.org/](http://www.rtaexchange.org/)

The RTA Exchange is jointly managed by Marie Chamay, Director of Strategic Initiatives, and Christophe Bellmann, Senior Resident Research Associate, with the support of Emily Bloom, Project Officer, RTA Exchange at ICTSD; and Antoni Estevadeordal, Manager, Integration and Trade Sector, Jeremy Harris, Economist and Integration and Trade Specialist, and Julia Muir, Trade Consultant at the IDB.

This think piece is one of a series of papers developed by the RTA Exchange that explore regulatory coherence. The series is managed by Rashmi Jose, ICTSD Senior Programme Officer, Investment and Regulatory Systems.

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**Citation:** Carberry, Robert. 2017. *Regulator Considerations: Leveraging Opportunities through Regulatory Cooperation*. RTA Exchange. Geneva: International Centre for Trade and Sustainable Development (ICTSD) and the Inter-American Development Bank (IDB). [www.rtaexchange.org/](http://www.rtaexchange.org/)

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ISSN 2520-2278

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## **| Abbreviations and Acronyms**

NAFTA	North American Free Trade Agreement
NGO	non-governmental organisation
RCC	Regulatory Cooperation Council
SPS	sanitary and phytosanitary
TBT	technical barriers to trade
WTO	World Trade Organization

## **| Abstract**

This paper examines the opportunity that regulatory cooperation provides to rationalise the array of overlapping international regulatory systems going forward, and the role that trade agreements can play to facilitate this occurring, particularly with regard to lessons learned from the Canada-US regulatory cooperation effort. In so doing, the paper outlines the context for cooperation between regulators, the important role for stakeholders, the approach to regulatory cooperation planning, and potential trade agreement implications.



# 1. Introduction

This paper will draw upon lessons learned through the first five years of the Canada–United States Regulatory Cooperation Council (RCC), the broader context in which that work occurred, the opportunity that regulatory cooperation provides to rationalise the array of overlapping international regulatory systems going forward, and how trade agreements might facilitate this occurring.

In its initial stage, the RCC work plan was comprised of a series of initiatives that were almost entirely of immediate concern to industry stakeholders and were already at various stages of discussion with regulators in either country. The RCC was seen as an opportunity to draw attention to these issues in binational Canada-United States (US) regulator discussions. The longer-term goal of the RCC, however, was not simply to address an ongoing series of individual initiatives, but to seek a mechanism to avoid the emergence of unnecessary requirements or misaligned approaches into the future.

Consideration of what was causing the creation of misalignments between Canada and the US and how to achieve an ongoing mechanism to avoid them exposed a consistent trend across sectors. Manufacturing is evolving, and the direction of that evolution is toward greater integration and consolidation globally. Also, the delivery of regulatory mandates through domestic regimes when applied to regionally integrated supply chains (in the Canada-US situation) and global value chains (Canada/US/others) — including the increasing predominance of global products — is increasingly questionable. When regulators repeatedly apply their regulatory regimes on the same products and supply chains, redundant or unnecessary requirements and costs are created.

As industry has moved to integrate and consolidate manufacturing, there has not been a commensurate response by regulators to determine how they might deliver their regulatory mandates in partnership with

other countries to address shared supply chains and common products. In the Canada-US situation, the two countries have the most integrated economies in the world, but maintain highly independent regulatory systems.

This has resulted in a broad range of unnecessary and duplicative requirements across sectors, and further globalisation will certainly provide a steady stream of opportunities for cooperative work. While regulatory departments and agencies in the two countries work well together, a more institutionalised form of cooperation or partnership had not been contemplated. The RCC discussions provided a forum to discuss opportunities between regulators and importantly with industry stakeholders, who have a key role in informing regulator discussions about industry trends and specific opportunities for regulatory cooperation.

It is timely for trade agreements to include text on regulatory cooperation and provide for regulator-to-regulator discussions. The Canada-US regulatory cooperation effort was advanced without reference to any specific trade agreement; however, it benefited from strong specific commitments from the leaders in both countries. Regulatory cooperation is the next stage, beyond tariffs and technical barriers to trade (TBT) / sanitary and phytosanitary (SPS) measures, in the evolution of removing unnecessary requirements for trade. Trade agreements are well placed to establish the imperative for a more systematic and ongoing dialogue on regulatory cooperation between countries.

This paper will outline some of the key aspects of the Canada-US regulatory cooperation effort, the context for cooperation between regulators, the important role for stakeholders, the approach to regulatory cooperation planning, and a potential role for trade agreements.

## 2. The Canada-US Experience and Traditional Regulatory Approaches

The Canada-US regulatory cooperation effort emphasised the importance of having initiatives and work-plans led by regulatory departments, differentiating it from previous exercises, which had been led through trade departments. The goal was to ensure the heads of regulatory agencies were primarily accountable for the commitments from the countries' leaders. In turn, the overall strategy and oversight was provided from the centre of government in both countries (Privy Council Office in Canada and the White House Executive Office Branch in the US).

Opportunities were identified through public solicitation from both industry stakeholders and regulatory departments on both sides of the border. The selection of initiatives in the initial joint action plan was crafted to avoid the stalemates that had occurred in previous efforts. Importantly, there had to be a willingness by regulatory departments in both countries to address an issue jointly. This had the effect of eliminating longstanding unresolved trade irritants or one-way barriers from the scope of the regulatory cooperation effort. In these situations, there were other SPS/TBT or broader issues to be addressed first, and they were not seen as ready for regulatory cooperation discussions. The scope of the work focused on departmental health and safety and environmental protection mandates, and did not venture into services or finance. There were tremendous opportunities for regulatory departments with those mandates, and it was felt the areas of services and finance did not have the same nature of issues.

From the outset, the scope of the work was not limited to aligning a regulation or a standard per se. It was recognised that the activities within the regulatory system were what generated the unnecessary requirements and costs to stakeholders. Even if a

regulation, or a standard, or an approval procedure in the two countries was identical, it was still being done twice, generating duplicative requirements and costs. This led to a vertical view of the regulatory system — starting from the initial consideration of an area to regulate through regulation development, policies, programming, compliance, and testing regimes — and the inclusion of all these aspects was placed in the scope work of regulators and was each an opportunity for cooperation.

As the work began, it was immediately evident that regulators in both countries were always seeking the same desired health and safety or environmental protection outcomes. Misalignment occurred simply because regulatory systems had been worked on independently. Approaches were not aligned, as regulatory systems development had been undertaken with a traditional domestic-centric predisposition from the outset. Regulators were not conditioned to see each other as competent willing partners in addressing an integrated supply chain or the same product being offered for sale in both markets. It became increasingly clear as the focus moved beyond irritants that there was an abundance of opportunities across regulatory systems.

A greater awareness of the opportunities became clear; delays in adopting the same energy efficiency standard for appliances was affecting the availability of new technologies in the Canadian market; product classification differences for lip balm led to vastly different approval processes and costs for the same products in the two markets; independent and non-synchronised standards for child safety seats in either country created a situation where individual manufacturers had to alter specifications for large retailers operating in both Canada and the US. All these products already had free access, but with Canadian and US regulators operating independently, unnecessary costs and dissonance in the value chain became apparent.

Both the Canadian and US governments benefit from world-class, highly developed regulation/rule-making procedures and policies. And both governments

have installed in their policies a requirement for regulatory departments to consider trade obligations and international trading partners when developing regulations. Yet, this requirement had been in place for some time, and the Canada-US regulatory systems were not aligned. However, this was before regulatory cooperation in the manner explored by the RCC was even anticipated. As awareness of the regulatory cooperation effort and expectations of it grew within regulatory departments and with stakeholders, there was a new dialogue concerning what was expected by those involved in or implicated by regulatory systems. Simply put, a deeper form of cooperation had never been contemplated and the policy instruments could not have been expected to drive that nature of alignment. As regulatory cooperation is advanced, more robust and specific policy instruments and interpretations will be needed to establish a path for regulatory departments.

### **3. External Realities — Shifting Context for Domestic Regulators**

Regulatory departments are continually challenged to keep pace with technological advances, new products, scientific innovations, and a rapidly changing international production and manufacturing landscape. Without question, there has been a shift away from domestic production to one of greater regional supply chain integration and global value chains, including an increasing trend towards global products. This poses a significant challenge for domestic-centric regulations in an increasingly global production and manufacturing reality. Applying multiple country requirements on individual integrated supply chains results in unnecessary and duplicative actions and costs. An individual supply chain is subject to each of the government's requirements. They all intend to provide the same regulatory outcome, but they are doing it independently.

There is a trend toward globalisation of value chains that is apparent across all sectors, albeit at different speeds and levels of evolution. Because the airline industry has been flying from one country's air space to others for decades, airline safety regulation has approached a high degree of global alignment. Pharmaceutical drugs and their components are being produced through increasingly global supply chains, and regulators are faced with how to achieve their safety mandates in other jurisdictions. Also, as manufacturing consolidates, multiple countries are pondering their approaches on those same jurisdictions. While sectors are at different places on a continuum from domestic to global, they are all trending toward more international integration. Regulatory systems are constantly challenged to keep pace with this trend.

Global products, those being manufactured to the same standards and through the same technologies, are of increasing interest to manufacturers. However, single products still require individual approvals and scrutiny in each of the countries in which they are marketed. This creates cost in each individual jurisdiction and repetitively for manufacturers. Cooperation between regulators in developing standards and ensuring compliance would reduce costs to manufacturers, regulators, and consumers.

Adapting regulatory systems to track with these trends will require cooperation between regulators across jurisdictions. Regulatory cooperation discussions can provide the ideal venue for regulators to discuss challenges and opportunities and to form regulatory partnerships. Regulatory cooperation should be positioned as an opportunity for regulators to address common challenges.

## 4. Role of Stakeholders

### 4.1. Industry Stakeholders

During the Canada-US RCC effort it became clear that government was not well placed to identify where regulatory alignment efforts should be directed, as there is a low level of specialised knowledge of industry operations, the impact of regulations on them, and their related costs. When industry stakeholders took it upon themselves to identify impacts and provide the related cost analysis, it became even clearer that this responsibility was best left to them. Industry stakeholders identified areas of significant opportunity where alignment was thought to already be in place.

In addition, there was a degree of foresight industry stakeholders brought to discussions that served notice to regulators that new areas were emerging that would require attention. This facilitated a longer-term view and allowed for earlier coordination between regulators on some matters.

Given the relationship between industry trends and regulatory systems, industry stakeholders have a role to play in regulatory cooperation discussions — primarily in the area of providing cost — demonstrating the benefits of regulator efforts to align and in providing insights to regulators on current and future industry changes that will impact regulatory systems.

### 4.2. Other Stakeholders

Care was taken at the outset to avoid the pitfalls of some potential criticisms or misunderstandings about regulatory cooperation. Namely:

- Race to the bottom: to avoid this, initiatives were undertaken, which represented an improvement to the regulation as it applied to health, safety, or protection of environment by both governments.

- Loss of sovereignty: it was made clear that scientific work could be an area for collaboration; however, final approvals and decisions would always be made in each jurisdiction. In this respect, alignment was not a “policy decision” to align at all costs. If a jurisdiction decided not to align, and there was discussion and work conducted with alignment as a possibility, that was acceptable. The RCC simply wanted to ensure that discussions took place.

- One regulatory system across both countries: it was made clear that both countries would maintain separate regulatory systems and agencies, but that greater partnership and synchronisation of work was the goal, such that duplication and unnecessary requirements would be eliminated as alignment was achieved.

These messages were in all communications materials from the outset of the work of the RCC, and these storylines fortunately did not overtake the exercise.

From the standpoint of consumers and non-governmental organisations (NGOs), there was not any acute interest in the work of the RCC. However, the consumer benefit aspect was not predominant in the early discussions or work of the RCC. In Canada, sessions were held with consumer groups when they were brought together by other agencies, and they were apprised of RCC progress. In addition, all sessions and requests for submissions for the RCC were open to the public and interest groups in addition to industry stakeholders.

## 5. Regulatory Cooperation Planning

At the outset of the Canada-US RCC work, the exercise was broadly seen as a continuation of a series of efforts to address trade barriers and irritants between the two countries, and ideas generated for potential inclusion in the initial work plan were identified in this context. One way irritants were excluded, as previously mentioned, and an effort was made to expand individual issues into what they represented and not simply what they were was undertaken to generate the discussion of more systemic issues between regulators. This then expanded into what further opportunities may be present in those specific areas of regulatory business (e.g. product review and approval) in various subsectors. Ultimately, it became clear that tremendous opportunity did exist. It was also apparent that regulatory alignment should be the product of very early discussion between regulators, at the time of the contemplation of whether to regulate or not, far before a regulation was being proposed. Once a regulation is proposed, there is already significant momentum created within jurisdictions. Once decisions have been made and rationales developed, material changes are difficult to achieve.

In the Canada-US RCC, the identification of opportunities for alignment and efforts to incorporate them into regular departmental regulatory strategies and planning cycles at early stages was seen as critical. This was necessary to shift regulatory cooperation as a competing priority to a matter of "business as usual." Discussions between jurisdictions related to regulatory cooperation planning was seen as a game-changing institutional measure.

Commitments were made between similarly mandated regulatory departments to meet annually specifically to discuss regulatory cooperation. These meetings were not intended to discuss issues or technical matters. Rather, those responsible for the

overall regulatory systems in each agency would meet to focus on the medium- and long-term to determine where cooperation might be of benefit to each going forward.

These meetings included sessions where industry was asked to outline sectoral trends and areas where regulatory systems may need to be directed, considering what new innovations, technology, and products were on the way, so regulators could contemplate what was needed in the future. Further, they were asked to share overall manufacturing trends related to supply and value chains and to provide their thoughts on what might impact the regulatory system.

Unlike issue-based technical work plans, these meetings are seen as critical as they serve to bring industry and regulators between countries together in a forward-looking context and create a new type of dialogue around regulatory cooperation.

The issue of bringing in other countries, primarily Mexico, in the case of the Canada-US RCC was often raised. There was a formal invitation to Mexican officials to attend meetings of the council and the planning plenary sessions for annual planning. While this was not intended to create tri-national plans, it was thought to be helpful in raising awareness about what Canada and the US were contemplating and encourage consideration of directions for their own regulatory regimes.

Beyond this, in the supply chains that Mexico participates in, alignment between Canada and the US is of some benefit, as it provides a uniform production opportunity for Mexico, and the creation of a domestic regulatory regime is not a prerequisite for benefiting from regulatory cooperation. For example, Mexico is a full participant in automobile manufacturing in North America. Aligning a standard for the construction of a vehicle between Canada and the US facilitates Mexico's participation in that production. Importantly, Mexico does not need to put a regulatory system in place that is aligned to Canada and the US, it simply needs to produce to that standard for the Canada/US market.

In this scenario, the regulatory system does not need to exist within Mexico, and in fact it may be easier for Mexico to adjust to new Canada/US standards, as no regulatory change would be required in that country. Countries with the most robust, complex, and long-standing regulatory systems face greater challenges in moving off the status quo and aligning standards between themselves.

The opportunity for regulatory cooperation in each country is unique, driven by specific situations of manufacturing integration and cross-border relationships that are product-category specific in most cases. Regulatory departments will need to develop their own internal regulatory cooperation strategies, deciding on what, with whom, and when to align or partner.

## 6. Trade Agreement Implications

To facilitate informed discussion and consideration of how to include regulatory cooperation in trade agreements, common definitions around the various, often overlapping terms, is required. Terms are emerging in international materials that refer to good regulatory practices, regulatory coherence, regulatory cooperation, and so forth.

### 6.1. Good Regulatory Practices

Good regulatory practices refer to transparency, consultation, notifications, and other aspects of developing and implementing regulations. Good regulatory practises are a pre-requisite for any work on regulatory cooperation. Without these fundamentals in place, there is no predictability to allow for advanced forms of work between jurisdictions, such as regulatory cooperation. This is a separate issue, and rolling this into discussions on regulatory cooperation leads to misunderstanding. There is a role for trade agreements in this respect,

but care should be taken to separate this aspect from regulatory cooperation, as agency roles and the process of advancing cooperation or conducting good regulatory practice are entirely different.

### 6.2. Regulatory Cooperation as an Evolutionary Step

Regulatory cooperation requires willingness between similarly mandated regulatory departments to engage in discussions and to work toward a cooperative approach in achieving their regulatory mandates. It requires primary ownership on the part of the regulators; they will need to see the advantages of working with the other authority(s) in partnership.

The World Trade Organization (WTO) rights and obligations and related mechanisms, including dispute resolution, have been successful and continue to be the appropriate place and manner in which to address the impediments to trade for which they were intended.

Regulatory cooperation is ideally suited to be applied once the tariffs and TBT/SPS issues have been cleared away and markets have been established. Considered this way, the WTO is clearing the way for trade, and regulatory cooperation can optimise the efficiency of the trade flow with respect to regulatory matters. These next steps in facilitating trade are through the removal of unnecessary or duplicative requirements and their associated costs. It works best where market access is well underway, overall risk mitigation has been successful, and the nature of the opportunity merits the time and effort for its pursuit.

### 6.3. Policy Option Considerations

While the Canada-US RCC was initiated absent a North American Free Trade Agreement (NAFTA) clause, it did benefit from a specific commitment and renewal of that commitment between the Canadian and US leaders over the last six years. The issue of what would be the nature of any inclusion in future

trade agreements, regional or otherwise, even at a multilateral level, should entail consideration of the following:

#### Regulatory department leadership

- Stakeholder input in identifying short-, medium-, and long-term opportunities
- Using an “optimising existing trade” and not an “irritant” lens
- Willingness and opportunity as the driver, not rights and obligations
- Regulatory cooperation opportunities will be most apparent in integrated supply chains (upstream) and for global products entering markets (downstream).

— Given this, regulatory cooperation activities will neither be limited to parties within a trade agreement nor necessarily be inclusive of all parties within one, and will vary across subsectors.

The inclusion of regulatory cooperation in trade agreements should institutionalise regulatory cooperation discussions and planning between regulators. As the goal is discussion between willing partners, a requirement that would bring similarly-mandated regulatory departments together to identify opportunities, including sessions with industry stakeholders, would be essential. Importantly, it should recognise that non-signatories to any specific agreement may be included in the development and implementation of regulatory cooperation work plans depending on the nature of the opportunity.

As such, the concept of a “hub and spoke model” described by Mavroidis and Bollyky (2016) is generally valid, but not through a traditional country-to-country trade policy lens. Regulatory cooperation should be considered an opportunity for regulators to do their jobs more effectively and efficiently through regulatory cooperation where global value chains

exist. And, the expectation that the regulators will meet to pursue those opportunities should be paramount. Regulatory cooperation requires discussion between the implicated parties, and no institutionalised forum has been generally established.

Industry stakeholders should also have a role, ideally in identifying potential initiatives and emerging opportunities, and opportunities for their submissions should be considered.

## 7. End Comment

Regulatory departments embrace their health, safety, and environmental protection mandates and are focused on achieving the best results for their countries’ citizens. Globalisation in its various iterations, where manufacturers between countries are integrating production and where global products are seeking equal access to multiple countries, is making a domestic-centric execution of these mandates less and less viable. Partnership between regulators is an ideal means to extend reach through value chains, and regulatory cooperation discussions provide an opportunity to chart a path forward. Trade agreements can provide the necessary impetus for these discussions to take place. But, the primary lead should be the regulatory departments, who will need to see the opportunity to more effectively and efficiently deliver their mandates.





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