

MAKING A GOOD THING BETTER:

FINISHING WHAT WAS STARTED AND LEVERAGING NAFTA TO ADVANCE CANADA-U.S. REGULATORY COOPERATION

By: Robert Carberry¹

Author's Comment

I worked in the Canadian Federal Public Service in all aspects of the regulatory world for 37 years. I've sat across negotiation tables on technical market access issues with dozens of countries, hundreds of times -- and many of those with the US and with Mexico. For the last five years of my public service career, I was asked to build a bridge between our governments -- by developing a strategy to advance and implement regulatory cooperation with the United States. And, with a dedicated team in Canada's Privy Council Office that worked closely with our U.S. colleagues in the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget within the Executive Office of the President, we successfully laid the groundwork for a new regulatory relationship between our two countries.

My assessment is that regulatory cooperation represents the next stage of evolution between mature regulatory systems. The current model is creating both unnecessary costs and duplicative administrative requirements that are negatively affecting consumers, regulators and regulated parties. Regulatory cooperation is the primary vehicle to bring greater recognition and cohesion between our regulatory systems. When I left the public service, we were at a point of implementing new processes between our regulators and making other changes that would secure regulatory cooperation going forward. However, my view is that momentum and meaningful progress has been lost. The recommendations in the following report are an elaboration of the path we set for binational regulatory cooperation through five years of work. With an uncertain future for Canada-U.S. regulatory cooperation, I believe that urgent action is

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required to re-establish the trajectory towards success, and NAFTA discussions provide a significant opportunity to establish a new regulatory relationship between our countries.

Purpose

This paper provides a comprehensive framework for the use of the Canada-U.S. Regulatory Cooperation Secretariats, NAFTA negotiators and a range of stakeholders directly benefiting from a robust regulatory cooperation effort. It will examine why regulatory cooperation is required, where it is best applied, and what is needed to institutionalize it between Canada and the United States. This paper will focus on Canada-U.S. issues but it will also identify how NAFTA provisions could help secure and position regulatory cooperation for Mexico as well. Through the NAFTA negotiations and prospective agreement, there is an opportunity to set an example for the international community contemplating how to best approach regulatory cooperation as the next stage of evolution in trade facilitation between countries.

Evolution

The global manufacturing and trade environment has changed dramatically in the last 20 years. Individual product supply chains are rarely contained within single countries and, in many situations, participants in those chains are spread across the globe. Further, manufacturers are seeking to produce standardized, global products for markets around the world at the same time as consumers are demanding affordable, high-quality and safe products.

There are no better examples of integrated production and consumer markets than in Canada and the United States. We manufacture products together and our consumer markets are characterized by the same risk tolerance and preferences. However, while our manufacturing and markets have integrated, we have not achieved much integration between our highly successful but independent regulatory systems, resulting in misaligned and/or redundant regulatory requirements on manufacturers, supply chains and products. The presence of two regulatory systems translates into unnecessary cost to manufacturers, consumers and to government agencies responsible for health, safety and environmental protection outcomes. Regulatory system design simply hasn't kept up with the reality of the manufacturing and trade world.

In 2010, recognizing the high degree of integration of the Canadian and U.S. economies, efforts to secure greater regulatory cooperation and alignment

between Canada and the United States began. Closer alignment between Canadian and U.S. regulators was seen by leaders and business as an opportunity to eliminate or reduce unnecessary and duplicative costs while maintaining or improving health, safety and environmental protection.

The early approach to identify opportunities for workplans between regulatory agencies was coordinated centrally in both countries. Ideas were solicited from stakeholders through the Canada Gazette and U.S. Federal Register. This approach was not particularly sophisticated, but it was familiar to government and industry and was intended to get the ball rolling, to socialize the notion of regulatory cooperation, and build momentum for the concept. A modest list of 29 areas of work was identified to start, but this was recognized as the tip of the iceberg. Each of the initiatives represented hundreds of other potential areas of work and would serve to establish a new type of engagement between regulators and with stakeholders.

The next waves of opportunity identification became less centralized and encouraged deeper discussion between regulatory departments and industry stakeholders. Through three rounds of planning over the first five years, hundreds of individual initiatives were undertaken. The regulatory cooperation secretariats in Canada and the U.S. always focused on a longer term goal of establishing a self-sustaining process at a departmental level that would advance regulatory cooperation as a new type of binational engagement between regulators and with stakeholders.

Finally, in 2015 a more sophisticated process was introduced by the regulatory cooperation secretariats in Canada and the U.S. that included a commitment to an annual planning cycle that featured primary accountability between similarly mandated Canadian and U.S. regulators. It was envisioned that the role of the centre of government would shift away from soliciting technical work plan opportunities, and be one of planning facilitation, ensuring that new binational processes were adopted, that ambition was high and intra-departmental coordination maintained.

The approach highlighted annual senior-level discussions directly between stakeholders and senior departmental officials to:

- inform overall regulatory system directions;
- identify opportunities in the short, medium and long term for alignment,

- update and enhance workplans; and
- ultimately, evolve and implement regulatory systems in partnership.

This new approach would be secured through strengthened governance that would ensure greater accountability at the departmental level, changes in central regulatory policy and a deeper understanding of how regulatory cooperation should be integrated into traditional trade policy.

The evolution of the Canada-U.S. Regulatory Cooperation Council (RCC) between 2010 and 2015 yielded significant progress for individual sectors and products but the ambitious framework envisioned to institutionalize and sustain momentum for progress has not yet been secured. The annual planning cycle has not moved ahead on schedule, and stakeholders are concerned about regulatory cooperation achieving its potential. Several measures need to be put in place to secure regulatory cooperation as the “new normal” for regulators. The current NAFTA discussions between Canada, the U.S. and Mexico, as well as the policy changes under consideration for the Canadian federal government’s Cabinet Directive on Regulatory Management need to be more sophisticated and comprehensive if sustainable and lasting regulatory cooperation is to become a reality.

What Regulatory Cooperation Is and Is Not

There are common misunderstandings about what regulatory cooperation might entail. While the desired outcome between jurisdictions is largely the same, the specific situation between jurisdictions dictates the nature of the approach. The following list highlights some of the specific realities about Canada and the United States regulatory alignment prospects, gleaned from the first five years of RCC operation:

- Regulatory cooperation is not for everything being regulated. Regulatory cooperation opportunities exist both upstream, in supply chains, production and manufacturing and downstream, in marketing finished products. More opportunities exist between countries where supply chains are integrated (cross-border manufacturing) and where markets are integrated (similar products offered) and where similarly-mandated regulatory agencies are in place and are seeking similar health, safety and environmental outcomes. Having these three areas of convergence between Canada and the United States provides these countries with the most opportune environment for regulatory cooperation in the world.

Regulatory cooperation need only be pursued in those areas where unnecessary or duplicative requirements are in place that represent burden for stakeholders, and in those areas where regulatory cooperation can lead to more effective or efficient achievement of collective regulatory objectives.

- It works best in areas where misalignment is unintended. The first five years of the Canada-U.S. regulatory cooperation effort determined that the primary reason for misalignment was mostly because work wasn't synchronized or worked on together. We don't have different standards for child seats for automobiles because we love our babies differently, it's simply because we improve standards for them on different cycles. Lack of synchronization leads to twice the cost to the regulatory system and additional costs to retailers and consumers.
- It is not about creating a single North American regulatory system. It's about building bridges between our regulators who are doing the same work on the same manufacturing systems, supply chains and products so they can work more closely together and rationalize the regulatory system. Both countries maintain their own regulations, but with integration between them where duplicative effort exists (testing, approvals, risk assessments, verifications, conformity testing, compliance, etc.).
- It is not about adopting the requirements of the other jurisdiction, and racing to the bottom. Regulatory cooperation targets synchronized mutual improvements when things need updating or a new issue is faced. It's about aligning regulation, renewal and modernization schedules. Substantial results can be realized when it's time to improve and modernize some complex regulations, such as meat inspection. We can do so together and agree on a common program, deliver it together and stand down from separate requirements that two systems currently necessitate, and avoid the emergence of any new differences. That would result in a de facto deregulation, removing an enormous amount of cost and duplicative requirements while enhancing safety.
- There is no loss of sovereignty; this is critical for both countries. Each jurisdiction maintains its own decision-making authority in all aspects of regulation, standard setting, product approvals, enforcement activities, etc. However, if the regulators synchronize work, use common data sets, conduct risk assessments together, and examine options together, then

the likelihood of the same decisions – executed at the same time - is highly likely.

- It is not just about having the same regulatory requirements or standards. That would still mean everything would be done twice. Work between regulators includes the programs being used to implement a regulation, which is where duplicative inspections, tests, certification and administrative requirements exist.

The new generation and form of ‘de-regulation’ does not in any way signify standing down from seeking a health, safety or environmental outcome in any given area, as is the traditional connotation with the term. Rather, it recognizes that there are other competent regulatory partners with oversight on the same supply chains and manufacturing systems. Not only can increased cooperation and partnership between regulators reduce overall regulatory burden and cost, it can also enhance the effectiveness and efficiency of the collective regulatory system through greater partnership and an integrated effort.

Integrating Regulatory Cooperation with Trade Policy

Regulatory cooperation is not another tool to use to address long-standing trade irritants or barriers. The SPS/TBT² disciplines and other WTO principles and tools remain best placed to deal with irritants, especially those arising from differences over cost or competitive circumstances. Regulatory cooperation is the next stage of evolution of trade facilitation where working cooperatively has the tangible effect of removing unnecessary barriers. Once market access exists, regulatory cooperation can further refine the nature of requirements between countries, lowering the cost for traders and consumers. It is the next arena of international trade facilitation, but implies a greater role for regulators once other trade irritants have been dealt with. Regulatory cooperation has a foot in both regulatory and trade departments, and is an important addition to future trade policy.

In this next stage of evolution, trade departments and agreements can make an enormous contribution by establishing regulatory cooperation as a priority between countries and securing processes between countries for regulatory cooperation dialogue. This dialogue needs to be led by regulators

² Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) measures contained in the WTO and successor agreements.

and informed by stakeholders who have shared interests and responsibility for health, safety and environmental protection. Regulators will always have these goals as their primary focus, but need to apply a regulatory cooperation lens while when advancing regulatory systems. This new lens will need to be secured by regulatory policy that is held by central agencies in both countries.

What is Required to Secure Canada-U.S. Regulatory Cooperation?

There are a number of practical steps that must be taken to secure and enhance binational regulatory cooperation. Most of these policy enhancements are within the purview of the Office of Information and Regulatory Affairs (OIRA) in the U.S. and the Regulatory Affairs Secretariat (RAS) in the Treasury Board Secretariat (TBS) in Canada. These offices have policies and other instruments that establish the fundamental approach to regulation in both countries. Some key practical enhancements are discussed below.

Changes in Both Countries to Support Regulatory Cooperation In 2012, the U.S. issued an Executive Order on international regulatory cooperation. It provides OIRA with the role of coordinating regulatory cooperation across departments. Importantly, it also signifies a special consideration for regulatory cooperation workplan initiatives between the U.S. and other countries. This has the effect of distinguishing proposals in areas included in regulatory cooperation initiatives from the vast number of other regulations. It also provides them with specialized considerations that could not otherwise be made without overarching changes to procedures for all regulations. The nature of these special considerations ranges from using combined data on risk assessments and cost benefit analyses to provide for regional options through to joint consultation and finalization of aligned regulations generated through the regulatory cooperation process.

This distinction for regulatory cooperation and related workplans have not been made in Canada's Cabinet Directive on Regulatory Management for regulatory cooperation. Further enhancements to Canada's Cabinet Directive as well as the U.S. rules and specific to regulatory cooperation initiatives could include:

- Provide for the use of combined U.S. and Canadian data for regulatory option development and cost-benefit analysis in order to examine collective regulatory system and stakeholder impacts across both countries rather than domestically only.

- Enhance analysis to include implementation procedures and costs that might misalign or cause duplicative effort or requirements in a two-country context.
- Provide for simultaneous/joint Canada-U.S. consultation with stakeholders on products of regulatory cooperation workplans
- Provide for Canada-U.S. (RAS-OIRA and regulator-to-regulator) confidential dialogue through comment periods to ensure aligned proposals don't inadvertently get misaligned in final regulation adjustments.
- Provide an expedited/facilitated approval process that allows for the binational involvement of stakeholders and both governments in proposal development
- Require departmental development of regulatory cooperation strategies as internal documents aligned to Forward Regulatory Plans.

Strengthen Governance

The initial model for the Regulatory Cooperation Council did not work. There were no formal members, it did not meet regularly nor did it have any decision-making power. It was primarily the Canadian and U.S. teams in the Privy Council Office (PCO) in Ottawa and OIRA that drove the work without the oversight of any formal council. Canada benefited from a dedicated senior leader and team tasked with advancing regulatory cooperation as their only mandate. They worked closely with their OIRA colleagues who were highly skilled and committed to success but without the benefit of dedicated resources, they were taxed with competing priorities. To strengthen governance, future improvements could include:

- Re-constitute a Regulatory Cooperation Council led by the TBS Secretary/OIRA administrator that would include regulatory department heads with lead accountability for advancing regulatory cooperation. Meetings should be held annually to coincide with annual work plan development with stakeholders.
- Establish a formal Canada-U.S. Regulatory Cooperation Secretariat led by the Assistant or Associate Administrator of OIRA and an Assistant Secretary at TBS or PCO that would meet regularly and coordinate the activities of dedicated resources on both sides of the border.

Accountability, Leadership and Ambition

Since the initial formal commitment to binational regulatory cooperation on February 4, 2011, and after each of several elections on both sides of the border, leaders have continued to re-commit to regulatory cooperation between Canada and the U.S.. During this period, there was a gradual effort to shift primary accountability for regulatory cooperation, easing it away from the center of government towards regulatory departments. While central government is well placed to set direction through policy change and provide central coordination for regulatory cooperation advancement across government, regulatory cooperation depends on regulatory department leadership.

Ownership needs to be embedded at the level of regulatory departments. These organizations need to see regulatory cooperation as a vehicle to reduce regulatory burden, to increase regulatory system efficiency and to make the delivery of their health, safety and environmental protection outcomes more effective through partnership. And these partnerships need to be more structured and institutional to allow for joint efforts in a broad range of activities such as standard setting, risk assessments, testing, product review and approval.

Following are some recommendations to help entrench and expand the ownership of regulatory departments:

- Establish a formal oversight body between the U.S. and Canada comprised of government and industry representatives to ensure ambition is high. Industry stakeholders see regulatory cooperation as a primary vehicle to improve competitiveness and reduce unnecessary transaction costs. Their support provides an important voice to advance the overall effort.
- Enhance regulatory department analysis to include industry, consumer and departmental benefits of specific opportunities in a binational context. This includes contributions to burden reduction or deregulation.
- Initiate the development of new institutional partnerships between similarly mandated agencies to combine expertise to eliminate some of the currently duplicative activities through shared efforts.

- Task the Canada-U.S. Regulatory Cooperation Secretariat to develop a high-level competency in international regulatory cooperation and work with trade and industry departments to facilitate regulatory departments building strategies around it.

Planning

Through the early stages of the binational regulatory cooperation initiative, the centrally coordinated approach to identifying opportunities had inherent weaknesses. Soliciting ideas through an open call to stakeholders creates a focus on topical or short-term issues and allows for gaming between central agencies and regulatory departments on technical issues. It creates competing priorities for regulatory department plans that have already been set, and the one-off nature of proposals doesn't allow for broader strategic thinking. In addition, it became apparent that regulatory departments did not fully understand the operational effect that misaligned regulatory and implementation requirements have on individual businesses.

As the regulatory cooperation effort evolved, the value of stakeholder contribution in identifying opportunities and providing insights into impacts became clear. It was for this reason that annual, senior-level discussions between regulatory department officials and stakeholders became critical to the planning cycle. These discussions touched on overall industry trends, technological advancements and Canada-U.S. trade dynamics.

Such discussion helped to inform annual technical plans that could help regulatory departments prepare new processes to facilitate aligned efforts. To reduce participant travel costs and to ensure binational discussions occurred simultaneously, it was determined that the best way to proceed was to launch annual planning with a single event. That process was first launched in the spring of 2016 but has not occurred since.

To enhance planning, some future improvements could include:

- Re-commit to the annual planning cycle as previously outlined by the Canada-U.S. secretariat, emphasizing the importance of senior departmental officials responsible for overall regulatory system direction to meet with stakeholders to discuss short, medium and long-term planning.
- Provide formal procedures for stakeholders to submit regulatory

cooperation opportunities to departments, the secretariat/council, and the oversight body that includes a requirement for analysis and response by regulatory departments. This is similar to the petition process in some U.S. legislation.

- Require departments to publish a concise annual report on submissions received, current and future workplan initiatives and results

How Can NAFTA Contribute?

Trade agreements can include very specific technical elements, establish new rights and obligations, capture areas for greater work and trade facilitation between countries and outline the general nature of new partnerships and relationships. These agreements have a very broad scope and can either encourage gradual change or mandate a wholesale change of direction. Regulatory cooperation between Canada and the U.S. was never driven by NAFTA, but there are opportunities for the agreement to help advance and institutionalize the process of regulatory cooperation. Within the NAFTA text, changes can be bundled into the General Part, Good Regulatory Practices (Regulatory Coherence), a Regulatory Cooperation section, and the TBT/SPS chapter.

From an overarching perspective, the NAFTA can signal a new stage of evolution in the regulatory and trade relationship between Canadian, U.S. and Mexican regulatory systems to benefit the region. It can also serve to set a new paradigm for considering where opportunities exist and should be pursued. The NAFTA requirements should not be sector or product based, rather they should focus on establishing practical mechanisms and processes between the countries to advance regulatory cooperation. The areas for inclusion are summarized from principles and practices advanced earlier in this paper.

General Part – Objectives

- Introduce the concept of a new cooperative regulatory relationship - including greater alignment and partnership between the regulatory systems of the countries where appropriate.
- Provide for a broad range of institutional partnerships, joint arrangements and mechanisms between regulatory agencies to better align efforts for more effective and efficient collective

achievement of health, safety and environmental outcomes.

- Eliminate unnecessary regulatory duplication and administrative requirements that generate cost to business, consumers and regulatory agencies while continuing to achieve high levels of health, safety and environmental protection.

Good Regulatory Practice

- Establish a specific status for regulatory cooperation initiatives that are more focused than “international trading partner considerations”.
- Include the practise of assessing impact on the countries involved in a regulatory cooperation initiative collectively - using shared data, collective risk assessment, and cost-benefit analysis of collective implementation costs and impacts.
- Include a process for joint/simultaneous formal consultation on regulatory proposals stemming from regulatory cooperation workplans and a process for collaboration during comment periods and finalization of regulations.

Regulatory Cooperation Section

- Clarify that regulatory cooperation will be used only in areas where market access already exists and trade irritants are minimal. The focus will be on refining and rationalizing regulatory requirements
- Formalize governance – provide for a Secretariat and/or Regulatory Cooperation Council that includes regulatory departments with responsibility for workplan initiatives.
- Establish regulatory departments in the the lead role for regulatory cooperation planning and delivery.
- Institutionalize annual planning where regulatory cooperation councils exist.
- Formalize engagement with stakeholders to identify opportunities, generate workplans and provide information about overall industry directions and how they align with regulatory systems and priorities (a distinct process from the creation of formal regulatory proposals).
- Provide formal procedures for stakeholders to communicate

regulatory cooperation issues to departments, secretariat/council and oversight bodies.

- Recognize that work plans can be established between subsets of signatories and can include countries that are not signatories (see box below).

TBT/SPS

There is a unique opportunity in the NAFTA region given it is a contiguous territory and in some areas a contiguous consumer market. We can move beyond traditional country-to-country measures especially where these common consumer markets and preferences exist or where manufacturing systems/supply chains are similar or integrated.

This reality provides an opportunity to address risk to consumers once, through the same measures. It provides an opportunity to focus on supply chain or manufacturing system risk together, and address risks to our environment together (and not applying measures simply because something is crossing a border). There is an opportunity for our regulatory systems to be modernized together with a view to common programs and joint/mutually accredited delivery that would provide significant cost savings both to business and regulators.

The same requirements can exist across any set of countries. They can be international standards, regionally developed, or be commonly adopted from third parties. This latter element may also provide another opportunity. Should a system held by a non-governmental third party be recognized by a set of regulatory departments, and approved conformity assessment is in place, this could constitute equivalence between countries for that supply chain or product and no other requirements need apply.

Providing for the use of third party systems would open the door for other options in the NAFTA region. While some regulators would see this as blasphemous, the reality is that third party developed and delivered systems are already being employed in some sectors, and those systems are often at least as effective and reliable as anything in government. Opening the door for this as a possibility would be progressive, and set the stage for the next generation of more efficient and effective regulation in the region.

In summary, some specific SPS/TBT enhancements that could be included in

the NAFTA are:

- Recognize that specific opportunities exist as afforded by a contiguous territory within the NAFTA territory through integrated supply chains, our common manufacturing systems, a common risk tolerance and consumer market.
- Promote the use of jointly developed common requirements and programs that, once implemented, serve to satisfy the health and safety requirements of the other country, and are recognized as a SPS/TBT consistent measure.
- Provide for the recognition of third-party specialized safety systems and accredited third-party conformity assessment bodies as an alternative to governmental programs.

Managing bilateral and trilateral issues

Participation in regulatory cooperation workplans is driven by opportunities that exist within shared or common supply chains and markets. Opportunities depend on the existence and nature of regulatory regimes within each country. If two of the three NAFTA partners have specific opportunities, then the initiative can be bilateral. If NAFTA partners see benefits in aligning with other countries outside the NAFTA agreement, that as well should be pursued. This is simply to say that not all efforts are necessarily trilateral. However, full transparency should be practised among the three partners.

Conclusion

Regulatory cooperation, particularly in the Canada-U.S. context, has the potential to yield effectiveness and efficiency improvements in the delivery of regulatory department mandates, and simultaneously reduce regulatory burden on the manufacturing and production sector. Consumers will similarly benefit from improved outcomes in health, safety and environmental protection with cost savings from greater efficiency. But there is a considerable amount of inertia in the status quo, and regulatory departments need further direction, permission and an opportunity to advance regulatory integration and shift away from an independent, stand-alone perspective.

The reality is that manufacturing and production has already moved on. It has integrated across jurisdictions, and regulatory systems should be integrated in the areas where they are now creating unnecessary cost. The NAFTA could be very helpful in establishing greater aspiration, in signalling a new regulatory relationship between NAFTA partners, and providing a framework for this to occur. This would set a direction, and provide a new type of dialogue between regulatory agencies that will result in a more rational and integrated regulatory system across North America.





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