COUNCIL OF THE GREAT LAKES REGION

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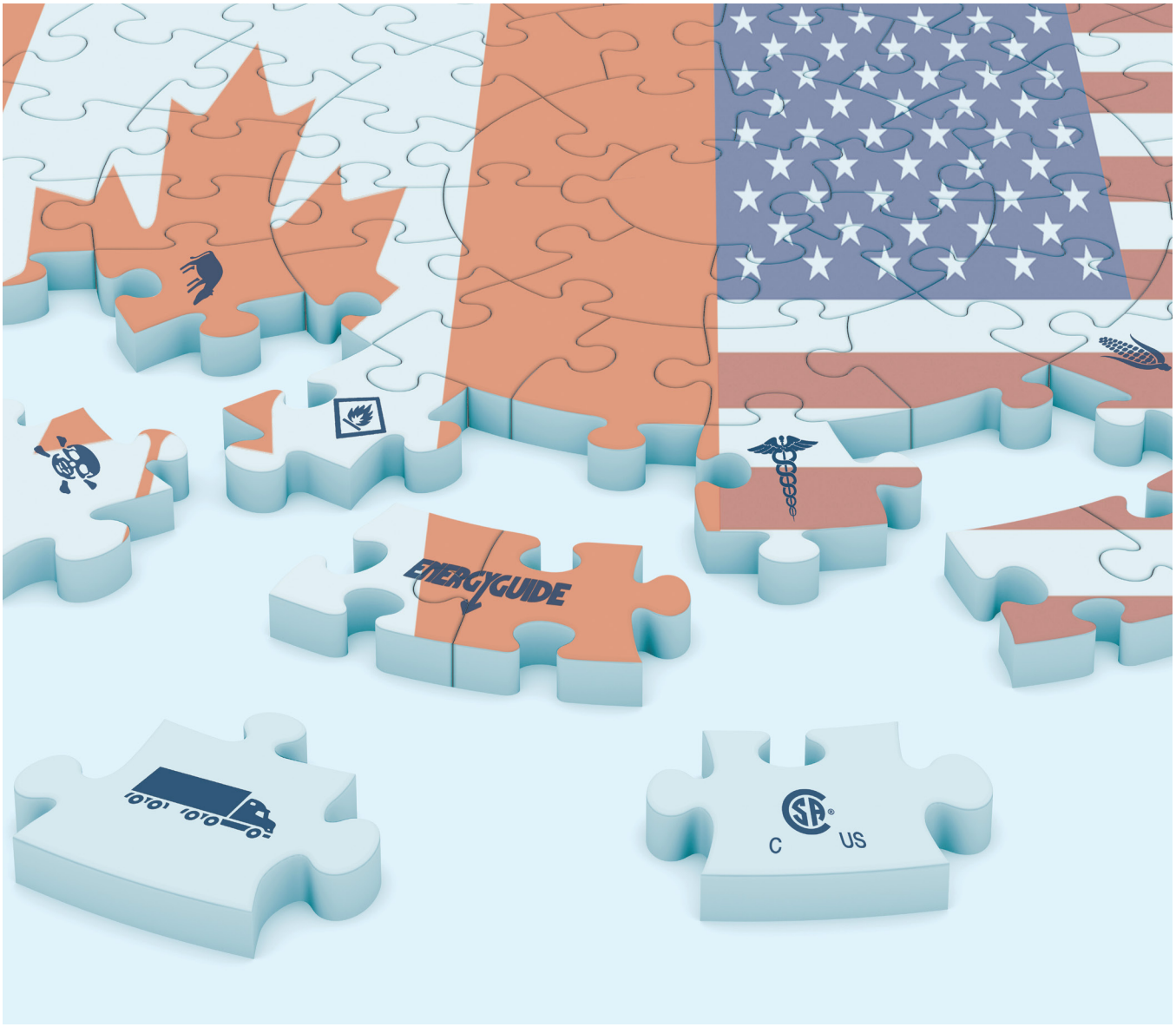
Untapped Opportunities

Advancing Regulatory Cooperation in the Great Lakes Region



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About the Council of the Great Lakes Region

The Council is a non-partisan, non-profit, bi-national organization committed to deepening the United States-Canada relationship in the Great Lakes-St. Lawrence Region, defined by the border states of New York, Pennsylvania, Illinois, Michigan, Minnesota, Ohio, Wisconsin, and, Indiana and the provinces of Ontario and Quebec. The goal of the Council is to create a stronger, more dynamic culture of collaboration in harnessing the Region's economic strengths while enhancing the well-being of its citizens and protecting the environment for future generations.

Executive Summary

This report provides a rationale for regulatory cooperation within the bi-national Great Lakes Region and proposes some potential first steps to initiate a dialogue between New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin, Minnesota, Ontario, and Quebec.

Regulatory cooperation is broadly seen as the next area of opportunity for facilitating trade between jurisdictions. The World Trade Organization (WTO), over 30 years, has all but eliminated tariffs and unfair trade barriers, and now that market access for most products is well established, there are legacy regulatory requirements that are creating unnecessary costs and burden on business, impacting consumers, slowing and limiting product availability, and raising costs. These legacy requirements were well intended and necessary through the years, but manufacturing and trade realities are providing an opportunity and imperative to re-examine how best to regulate commerce and protect consumers.

In the Great Lakes Region, multiple jurisdictions and orders of government place requirements on manufacturing the production of goods and other aspects of the economy like road safety, rules governing energy efficiency, waste management, and environmental protection. The federal governments of both countries invest heavily in the development, maintenance, and delivery of their regulatory systems that impact the Great Lakes economy; so do the states and provinces. Municipalities are also increasingly regulating industry in some areas through by-laws. At the same time, these systems were being built and refined, business was becoming more global, moving out of regions and out of countries as supply networks and value chains expanded.

This is a new manufacturing and trade environment, and industry stakeholders are faced with asynchronous and duplicative requirements for their varied operations and production. Traditional regulatory systems are bumping into each other as a result, and it is timely to consider how to achieve health, safety, and environmental protection mandates in this new setting. The good news is that these systems are all seeking to achieve the same outcomes, and through increased regulatory cooperation between jurisdictions, individual mandates can be delivered in a more rational, effective, and efficient way.

Borrowing lessons and insights from the Canada-United States (U.S.) Regulatory Cooperation Council and other practices internationally, this report outlines how to start a regulatory dialogue in the Great Lakes Region at the state-provincial level, how to structure new relationships and processes to advance the initiative, and how to provide for an ongoing dialogue in to the future.

Enhanced regulatory cooperation in the Great Lakes can be a game-changer, and it can be done in a way *that benefits* a wide variety of interests, from regulators and policymakers, to business and consumer advocates. Above all, it can help us achieve more efficient and effective government, reduced operating costs to manufacturers, and more affordable and safe products for consumers.

The Regulatory Environment

Traditional approach

In 1947, the General Agreement on Tariffs and Trade (GATT) set rules in order to reduce the proliferation of tariffs impeding trade post World War II (WWII). Since 1986, the WTO has steadily moved us closer to an even more rational environment for trade in manufactured goods, thanks in large part to its ongoing work in the area of Sanitary and Phytosanitary (SPS) protections and Technical Barriers to trade (TBT).

This work, however, led to a very 'domestic-centric' focus with respect to the development of regulations, as manufacturing supply chains were largely contained within each country. This approach became ingrained in the mindset of regulators. In fact, ask most regulatory agencies today what their primary mandate is, and they will tell you that they are focussed on achieving domestic health, safety, and environmental protection.

As a result, our 'regulatory system,' which refers to the regulation itself as well as the various programs, procedures, certifications, tests, inspection activities, and administrative requirements necessary to enforce the regulation, in almost all situations and sectors, can date its beginnings back decades – if not over 50 years. Many regulations, as a result, are products of evolution, often mixing together new standards with old approaches, with multiple priorities.

Consider regulations governing farm produce as an example. They contain health, safety and environmental protection requirements, grade standards and certification requirements, and package size requirements to promote orderly marketing. While regulatory agency mandates emphasize the health and safety requirements, other regulations applied to farm produce were designed to serve other purposes. Also, some health and

safety and environmental protection requirements, in the context of modern science and risk mitigation practices, now have a marginal benefit or certain redundancy.

Make no mistake: the WTO has been an unequivocal success. It required expert knowledge, extensive negotiations at a technical level, adjustments to almost all domestic regulatory systems, and an international effort to move past protectionist measures. The result has facilitated major changes in the manufacturing and production landscape across the globe.

But a new paradigm for regulators has emerged, as global manufacturing has evolved more quickly than regulatory models and systems. There is considerable scope for reconsidering how regulatory systems relate to each other. The WTO has cleared unfair obstacles to trade. Similarly, removing unnecessary or duplicative requirements and their associated costs through regulatory alliances is the next big idea for easing the flow of legitimate trade and advancing mature trade relationships between interested jurisdictions.

Private sector systems and standards

Private sector standards and systems include those that are developed through standard-setting organizations and are referenced through regulations as well as through voluntary application by industry. An example of the former is the Canadian Electrical Code, developed by the Canadian Standards Association (CSA), and adopted formally through regulation by provinces. Another example is the Global Food Safety Initiative, developed through the Consumer Goods Association in Belgium, which is adopted voluntarily by manufacturers and participants in their respective individual supply chains (including at the farm level).

Private-sector standards can be requirements of both manufacturers and large retailers, and are effective alternatives or complements to government regulation. This approach has the benefit of application beyond the scope of legislation and may be required by industry as a prerequisite to participation in individual supply chains that cross multiple jurisdictional boundaries. Their use provides assurance to manufacturers that all participants in their supply chain, whether foreign or domestic, are all meeting a range of industry expectations and standards.

Standards established through private organizations have the benefit of being highly practical, given their development by industry experts, and more responsive to changes in the various sectors. As industry stakeholders wish to protect customers and their reputation, and to prevent costs associated with failures, industry standards are emerging as an opportunity worthy of serious consideration by regulators as firms increasingly achieve health, safety and environmental safety mandates that meet or exceed those established by governments – sometimes on a faster implementation schedule.

Growing misalignment, cost of compliance, and administrative burden

Many jurisdictions and orders of government are interested in regulating. Governments want to make a difference and to be seen as responsible leaders in regulating commerce, protecting human health and consumers, and conserving the environment. This can lead to regulatory misalignment, which results in unnecessary costs and administrative burden.

Therefore, regulators need to work together, become more intimately aware of how and where regulations are applied, and determine whether risk mitigation has already occured.

There is always a cost to a regulated party when government steps in, and regulating should not just be seen as a safety measure. It needs to be seen also as a cost to industry and consumers, whether it is necessary or just trying to achieve something that has already been achieved by another order of government or jurisdiction..

For example, manufacturers and distributors of global products or products that are standardized for a region are experiencing layer upon layer of approvals, tests, and certifications, not only when a product enters the country, but also as it enters provinces and states. The product has already been manufactured to a standard set by its “primary” regulator at some point, and has been tested and certified through some process.

At best, setting even the same standard at another level of jurisdiction and requiring additional administrative actions by the manufacturer or distributor adds cost and delays getting products to market. It does nothing to improve the product or to provide additional consumer protection. At worst, it establishes a different standard that acts as a barrier to entry in the market and weakens the business climate.

Challenges to regulators

The ‘domestic-centric’ approach to regulation is inherently at odds with more globalized manufacturing where, supply chains cross borders multiple times in some cases, and are fed by increasingly segmented and specialized non-domestic sources. It is especially dated in the context of Canada and the U.S., where our economies are the most integrated in the world and supply chains have been shared for decades.

Simply put, a single product manufactured through an integrated U.S.-Canada supply chain is subject to world-class regulatory systems in both countries. Furthermore, a product imported from a third country, which is to be used in manufacturing intermediate or final goods, is also subject to either the Canadian or U.S. regulatory system, depending on its destination.

There is no better example of integrated North American manufacturing than the auto industry. Canada and the U.S. formed the "Auto Pact" in 1965 to move away from segregated Canadian and U.S. manufacturing of automobiles. This rapidly changed the manufacturing landscape and led to individual factories producing for both markets. The auto industry now cites seven cross-border transactions within its supply chain to assemble an automobile.

However, since 1965, both countries also developed sophisticated and highly successful safety standards, independently adding differing requirements at different times, eroding the originally intended economic benefit. Recognizing the unnecessary costs and administrative burden placed on the industry, auto regulators have begun to cooperate in an effort to align these standards. Their experience is now being repeated across other manufacturing sectors.

Two other examples of how manufacturing has evolved and the resulting challenge for regulators are on the breakfast tables of Canadians and Americans every day. Thirty years ago, most apple juice and honey was domestically sourced and manufactured, and regulatory systems established requirements for Canadian or U.S. product handling at the source through to processing and packaging. This enabled regulatory enforcement of safety requirements in all aspects of production.

Today, juice concentrates processed in other countries dominate the market. Honey labels now indicate source countries, such as China or Argentina. The issue for regulators is one of scope of coverage of regulations and ability to enforce their provisions through the supply chain. There is an increasing reliance on foreign establishments and regulatory authorities to apply similar requirements to those in Canada and the U.S. for products that are destined here for further manufacturing in Canadian and U.S. facilities.

Similar challenges also exist for products manufactured elsewhere for sale domestically. Industry is moving to global products to seek economies of scale in manufacturing and product promotion. Some sectors have been impeded by a lack of response by regulators in developing common product standards and regulatory approaches that would facilitate manufacturing for key markets, thereby increasing product cost that is ultimately passed on to consumers.

It is now timely to reconsider traditional regulatory approaches and seek ways to work with other jurisdictions with responsibilities on the same supply chains or who are assessing and mitigating risks from common sources. We are beginning to look for opportunities to reconcile regulatory approaches and strategies with some of the new realities in manufacturing and production. Certainly, the context for regulators is decidedly less 'domestic-centric' than it has ever been.

Case studies

Challenges faced by stakeholders when discussions between regulators lead to uncoordinated action are summarized below. Two situations that touch products in every home have been selected:

- Microbeads in personal-care products
- Energy efficiency – home appliances

Case Study One – Microbeads

Information on the issue outlined in this case study was provided by the personal-care industry. This issue is outlined for illustrative purposes only as an example of multiple jurisdictions independently contemplating regulatory change and the situation faced by the regulated industry during that period. It is not intended or offered as an exhaustive, objective analysis of the issue.

Context

Microbeads are small plastic spheres that were used in the personal care products industry beginning in the mid-to late 1990's. They were used as an exfoliant and provided gentle scrubbing action in lotions, cosmetics, scrubs, and similar products. They were gentler than the apricot pits, sand, and other forms of grit that were traditionally used in these products, and were broadly adopted across the industry.

Researchers studying the Great Lakes floor identified the presence of these microbeads in lake sediment and created awareness of their presence. While there was no specific scientific evidence identifying any deleterious effects due to their presence, some groups speculated these products might cause issues for aquatic life. Consensus science did not confirm this risk, but at the very least these products were litter, akin to water bottles floating in the oceans (it was estimated that beads represented less than 2% of all plastics in the waterways).

There was considerable media coverage beginning in 2008 on this issue as well as focussed attention by environmental NGOs, and large firms in the industry immediately moved to eliminate their use, not wishing to be seen in a negative light or contributing to a problem of any sort. Microbeads also emerged as a topical discussion by politicians in various jurisdictions, and calls for regulatory action to prevent the use of microbeads began to manifest themselves in the form of bills to amend legislation. These early regulatory amendment discussions originated at the sub-national government level and included a private member's bill in Ontario, Canada, and various U.S. states contemplating legislative changes.

Considerations

Personal care products are not specifically manufactured or formulated to address provincial or state differences. This sector is highly evolved towards the manufacture of global products. The products offered for sale are the same across Canada and the U.S. and their respective provinces, states and territories. The industry is not set up to adjust products at a sub-national level.

While all jurisdictions can pass legislation, it is principally federal authorities who have capacity to enforce regulations through inspection staff at manufacturing facilities and to enforce requirements when cross-border trade occurs.

National regulatory agencies in Canada and the U.S. had regulations in place at the time, covering the personal-care products industry as well as for environmental protection. Regulators in both countries and industry have traditionally worked to establish common national standards between Canada and the U.S.

Issue

The regulatory proposals under discussion in various jurisdictions were different in product definition (e.g. size and function of the beads), specific regulatory requirements, overall approach (e.g. some jurisdictions even considered some products as drugs so pre-approvals would be required) as well as coming-into-force dates. This was an impossible situation for an industry already manufacturing a common product across the marketplace.

Resolution

A considerable and costly undertaking ensued to engage regulatory authorities at multiple state, provincial, and national levels to coordinate the development of regulations. It is important to note that this was not an effort by industry to stop regulation, but rather to bring authorities to a consensus on a common regulation that would be consistent across the entire North American marketplace.

The industry worked closely with the State of Illinois which had proposed what was commonly seen as a reasonable bill, with appropriate and workable definitions as well as an adequate period for implementation including time for reformulation and sell-through of existing products. The bill also recognized that some products were classified as drugs and would require additional time for implementation, as reformulation would require the approval of regulators. The “Illinois model” was then promoted by industry to various state, provincial and national authorities as the best model to obtain a consistent approach by jurisdictions. As a national approach to the regulation of consumer products is preferable to state-provincial or local regulation, industry and other stakeholders were able to secure the passage of a bill in the U.S. Congress based on the “Illinois model” which was signed into law by the President as a national requirement.

In Canada, a resolution was unanimously passed by the House of Commons calling on the Government to bring in the necessary regulation through the mechanisms of the Canadian Environmental Protection Act, aligned with other jurisdictions. This resulted in the Government initiating a process under the Canadian Environmental Protection Act (CEPA) to enact an appropriate regulation which essentially followed the “Illinois model”. Following the launching of this federal process, the Government of Ontario decided not to regulate and a private members' bill was allowed to die on the order paper.

It is also interesting to note that although the U.S. and Canada have two very different approaches to regulation (the U.S. often preferring targeted bills or legislation, with Canada preferring to regulate under the authorities provided in existing legislation such as CEPA or the Food and Drugs Act), the end result was the same, as both countries ended up with the essentially same definitions and implementation dates.

The effort to achieve such alignment, however, did not occur because of cooperation and coordination between regulators, but rather because of the significant efforts of industry on both sides of the border to achieve this alignment.

Case Study Two – Home Appliances Energy Efficiency

Information on the issue outlined in this case study was provided by the home appliance industry. This issue is outlined for illustrative purposes only as an example of multiple jurisdictions applying differing energy efficiency regulations and standards simultaneously. It is not intended or offered as an exhaustive, objective analysis of the issue.

Context

The Home Appliance industry is fundamental to our modern lifestyle in North America. Appliances are present in every Canadian home in the form of refrigerators, freezers, stoves, washers, dryers, dishwashers, microwaves etc. While Canada participates in the North American supply chain to some degree, almost no manufacturing remains in Canada, having moved south and offshore over the last 2 decades. Imports[1] are more than $2.2B annually, with about 50% from the U.S., 25% from China and the remainder from Mexico and other countries. The U.S. is the largest manufacturer for the North American market.

Canada has had energy efficiency regulations since the early 1990s and they are administered by Natural Resources Canada (NRCan). In the U.S., the U.S. Department of Energy (DOE) administers them. With the interest in climate change, almost all jurisdictions have some form of strategy or rules around energy efficiency, including the municipal level, particularly in new home or building requirements.

There is little overarching coordination between the layers of jurisdictions about which standards to apply or how, with each jurisdiction making its own determination. The DOE is the *de facto* regulatory standard-setter and other jurisdictions align with their efforts to avoid dissonance in the marketplace.

Considerations

- Appliances are manufactured for the North American hemispheric market accordingly bilateral or trilateral harmonized standards. The products offered for sale are the same across the region. Production at a national or a sub-national level de-leverages all economies of scale and hemispheric advantage.
- There are three basic elements to Canada's energy efficiency approach;
  - *Energy Efficiency Regulations* that set minimum energy performance standards (MEPS). Regulations consist of energy efficiency standards, test procedures to determine efficiency, and methodologies to test products in a repeatable and consistent manner.
  - *EnerGuide* which is federal energy-efficiency labeling program and rating system required for importation and sale
  - *ENERGY STAR* is an EPA voluntary standard in the U.S. and Canada identifying products that have met or exceed technical specifications for HIGH EFFICIENCY. ENERGY STAR is a voluntary portion of the ENERGUIDE tag and is present for goods certified to be ENERGY STAR.

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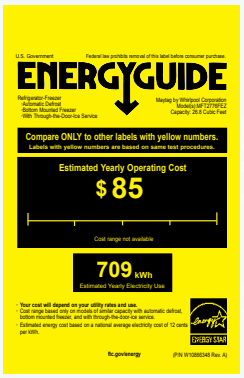
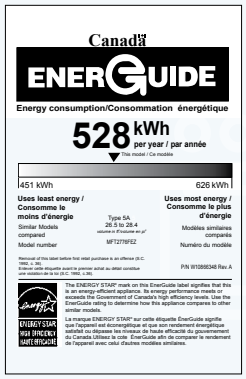
Issue

- Through the early 2000's, DOE rules were changed infrequently and U.S. energy standards remained relatively unchanged, which led some jurisdictions to propose their own regulations at a sub-national level. Both Ontario and British Columbia proposed to mandate the voluntary ENERGY STAR standard as the MEPS for sale in their province. Both these efforts were pushed back.
- From 2009 to 2016 the DOE and EPA accelerated energy efficiency rule-making for virtually all appliances in the U.S. The rule-making process involves assessment of technology, economic impact and modifications to test procedures.





- NRCan did not advance with the U.S.
- The industry was now faced with two sets of energy efficiency requirements and multiple test procedures including two methods for the determination of things like volume. This required contradictory labeling on products, with a label affixed to a single appliance with 2 different energy efficiency usage numbers and indicating 2 different volumes. Retailers were enormously frustrated with the confusion for consumers.
- Concurrently, provinces sought to proceed, in lieu of NRCan's inability to update federal requirements. Ontario enacted O. Reg. 404/12 referencing the DOE standard and test procedure, and, appliances carrying the U.S. Energy Guide label rather than the Canadian ENERGUIDE tag would meet Ontario's energy efficiency requirements per the regulation.
- O.Reg 404/12 requires 3rd party certification and labeling from an SCC accredited certification body. Other jurisdictions in Canada that regulate energy efficiency include these same requirements. Manufacturers must certify and label Microwave ovens for standby power requirements solely for the Ontario market increasing the costs to Canadian consumers.

Resolution

In 2017, NRCan passed "Amendment 13" aligning Canadian requirements with those of the U.S., a 7-year process.

However, in the interim, provinces have complicated the landscape. BC, Ontario, Quebec, and Nova Scotia have their own Energy Efficiency legislation, all causing additional administrative burden for industry. Ontario references the DOE standard, but continues to be the only jurisdiction that require a conformity label for microwave ovens. Canadian jurisdictions regulating energy efficiency do not follow the self-certification approach in the US, potentially creating additional costs for manufacturers. Other provinces reference Canadian CSA requirements in Canada's Energy Efficiency Act. Should U.S. and Canada misalignment occur in future, the issues referenced in this paper will be amplified once again.

Further challenges are emerging at the sub-sub-national level regarding labeling and requirements under new climate change strategies that are having the practical effect of banning products. For example, Vancouver has a zero-emissions building bylaw. This results in shifting all gas-fired appliances to electric only. There is little to no coordination of municipal building codes across the country that is creating additional administrative and cost burdens.

SECTION TWO

The State of Regulatory Cooperation

International trade

The WTO does not specifically provide for regulatory cooperation. However, there is ongoing attention to the role trade agreements play in furthering regulatory cooperation between countries. For example, there are efforts to bring together regulatory and trade policy representatives at the OECD, and initiatives like the RTA Exchange and other such fora to help inform such discussions. These discussions are still at early stages.

New terms and disparate definitions and understanding of regulatory cooperation, good regulatory practices, and regulatory coherence are flourishing. The way regulatory cooperation might be incorporated into trade agreements will clearly be the subject of more discussion.

At the very least, future trade agreements need to:

- Establish an expectation that regulatory cooperation will occur between countries where opportunities are apparent
- Establish regulatory agencies as lead for these efforts: advancing regulatory cooperation while seeking more efficient and effective ways to achieve fundamental mandates of health, safety and environmental protection through aligned efforts
- Secure a formal role for stakeholders in advancing regulatory cooperation and identifying opportunities
- Recognize that regulatory cooperation plans can exist among subsets of countries within trade agreements, and with others outside those agreements

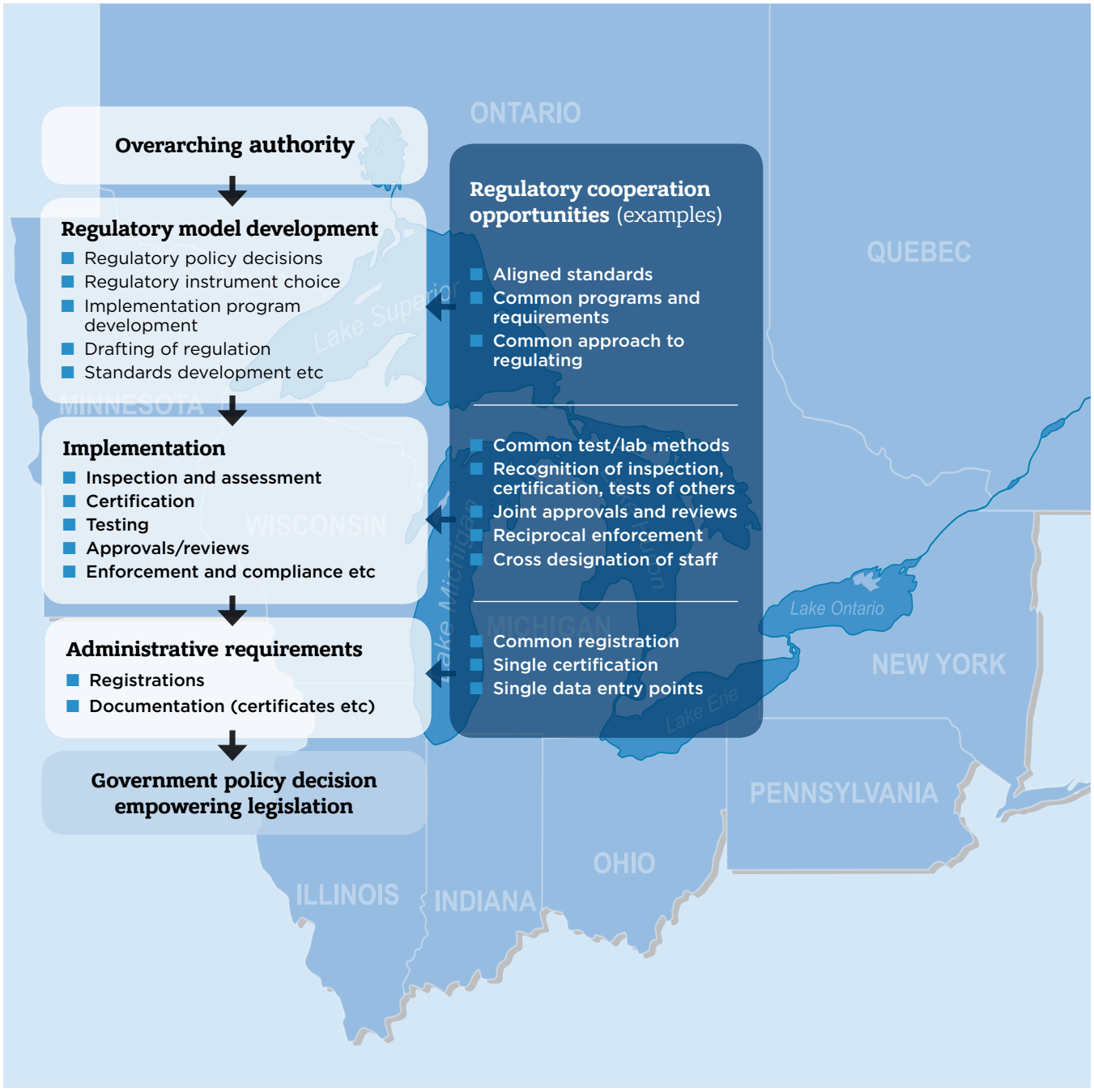
Bilateral and plurilateral trade

There have been some examples of trade policy shifting countries towards greater regulatory alignment, cooperation, and deeper partnerships, the most prominent examples being within the European Union (EU) and between Australia and New Zealand. Neither of these approaches are considered practical for application in the North American environment.

In the case of the EU, there is a considerable amount of centralized control by the European Commission that limits a member country's sovereignty over some aspects of regulation. If the Commission establishes a standard across the region, any individual country's ability to establish a different standard is limited.

In the case of Australia-New Zealand, new organizations were established for food standards and drugs that joined together each country's mandates in these areas and which report directly to the Parliaments of both countries.

DIAGRAM 1: Regulatory system and scope of regulatory cooperation



Most discussions to date are focussed on how to augment existing trade policy to introduce greater regulatory cooperation between jurisdictions. These discussions are ongoing, with much interest in the Canada-U.S. model. In this regard, discussions outside of North America are leaning towards creating regulatory cooperation processes, and not sector-based commitments.

Canada-U.S. efforts

An important effort in regulatory cooperation was initiated in 2011 between Canada and the U.S. To launch this as a first step and consider ongoing mechanisms to avoid misalignment of regulatory systems into the future, the Prime Minister of Canada and the President of the United States agreed to form the Regulatory Cooperation Council (RCC) between the two countries. The motivation for this initiative was not to pursue some new regulatory theory; it was to seek economic benefit for both countries.

There was an understanding that there were unnecessary costs related to independent, misaligned regulatory systems applied to integrated manufacturing and to the same consumer products, where risk tolerance and preferences were nearly identical. The RCC was intended to provide an opportunity to generate discussion between similarly mandated regulatory departments in the two countries and to identify opportunities for regulatory alignment.

It was recognized that unnecessary costs and duplicative requirements are not simply due to differences in regulations. Even if regulations and related standards were the same, each jurisdiction was applying its own requirements on stakeholders. So even if the approval process was the same for a given product in different jurisdictions, stakeholders had to incur the cost of two approval submissions, testing and inspection costs etc. The scope of discussions therefore was not simply about the regulation, but how it was being implemented in each jurisdiction and how greater partnership between regulators could reduce unnecessary and duplicative requirements.

A recent example of the necessity of getting to the actual implementation procedures and not just the legislation or regulation is the Food Safety and Modernization Act, where the U.S. Food and Drug Administration (FDA) worked closely with the Canadian Food Inspection Agency (CFIA) to recognize the Canadian system. While this took an enormous amount of work, and Canada's system was recognized, it did not result in any major changes to the nature or degree of inspections, tests, certifications, approvals, etc. required by the FDA for actual shipments or transactions originating in Canada.

Meat inspection and the requirements of the U.S. Department of Agriculture's Food Safety and Inspection Service is an excellent example. While 'equivalency' has been in place for decades, the system requires extra activities beyond Canadian regulation in Canadian facilities, re-inspection of products already deemed safe by Canadian authorities, and onerous certification requirements. These conditions result in enormous cost to safety, and Canadian producers and processors. Regulatory alignment efforts are intended to resolve these conflicts. This is where the real unnecessary and duplication-related costs reside.

Identifying issues for inclusion

Input from stakeholders was solicited through a notice in the Canada Gazette and U.S. Federal Register. Once these were in hand, discussions were held between federal regulators to determine what would be included in an initial action plan. Lessons from previous efforts led to the following approach:

- Regulators would have the lead accountability, and senior officials from their agencies on both sides of the border would form and jointly manage work groups.
- Initiatives would only be undertaken where there was a willingness on both sides of the border to consider changes in their regulatory systems. Long-standing one-way trade irritants were therefore not included.
- Initiatives where regulatory change was already being contemplated or underway were ripe opportunities for short-term work.
- Initiatives where there were not similarly mandated federal agencies or regulations in each country were not undertaken. Areas where sub-national governments had a substantial regulatory role or areas with voluntary or sub-nationally referenced third party standards were also seen as out of scope for the federal effort.

An initial Joint Action Plan was developed and, over the ensuing five years, two subsequent plans were developed, each increasing in scope and ambition. Importantly, the issue of developing an ongoing mechanism began to take shape over this time.

There were public commitments made by Canadian and U.S. regulatory agencies to jointly undertake an annual planning exercise and establish a process for ongoing stakeholder engagement in the short-term and, and to discuss industry trends and how regulatory systems might be jointly developed and further aligned in the medium and longer term.

The first of these sessions was held between regulatory agencies in Washington D.C. in 2016, with a commitment to a common annual planning process to be held each spring. Several considerations for success were identified:

- Industry stakeholders have an important role in helping regulators understand the impact of regulations on their operations, and in discussing the emergence of new technologies, industry trends, and supply chain changes that may impact regulatory systems. These joint discussions between stakeholders and regulators were strategic, not for individual regulatory proposals but in building a common understanding for the medium and longer term.
- A formally scheduled process should be institutionalized such that regulators and stakeholders are informing themselves in a predictable forum with common goals.
- Discussions need to take place in advance of regulatory proposals – these should contribute to proposals eventually – but, once proposals are made, options for change are limited.
- Regulatory cooperation needs to be institutionalized by regulatory agencies as an ongoing consideration in regulatory work, and incorporated into regulatory planning exercises, not as a competing priority, but as a means to improve the efficiency and effectiveness of collective regulatory systems achieving health, safety, and environmental outcomes.

The single most important element of successful regulatory cooperation is that discussions between jurisdictions need to occur well in advance of any regulatory proposals. Once proposals are put together, there has already been considerable momentum and commitment within regulatory agencies, and wholesale change is immeasurably difficult to achieve.

In addition, in the leadup to and as part of the work led by the federal RCC, pre-existing committees and mechanisms between various government departments and trade associations were recognized for their work in advancing sector-specific regulatory discussions; examples are the American Association of Motor Vehicle Administrators and the North American Commercial Vehicle Safety Alliance. Experience in the RCC has shown that industry groups had interests that crossed several sectors or departments. As a result, another important element of the RCC was the opportunity to support cross-sectoral discussions and engage regulators within a single two-day session.

This paper emphasizes the need for regularly scheduled discussions dedicated to regulatory cooperation planning between stakeholders and jurisdictions. These should be held in a single location simultaneously to accommodate the realities of multiple regulators covering individual sectors.

Avoiding misperceptions

The Canada-U.S. RCC exercise established some important principles during its initial stages to avoid any misunderstanding regarding its goals and how it would proceed. This served to avoid some of the negative perceptions regarding regulatory cooperation such as has been experienced in other countries and regions such as Europe. The principles included:

- Regulatory cooperation is not about establishing one regulatory system for Canada and the U.S. Both countries would maintain their existing regulatory systems.
- At no point would sovereignty be diminished; each country would make its own regulatory decisions (i.e. safety standards, product approvals etc); however, there was considerable work that could be done together leading up to decisions that would raise the potential of alignment (risk assessments, test methods, program design, inspection procedures, etc.).
- This was not a race to the bottom, rather Canada and the U.S. would cooperate and synchronize their efforts to improve the efficiency and effectiveness of regulatory systems to achieve health, safety and environmental outcomes.
- Regulatory cooperation is not a “policy decision” that requires alignment in all situations; rather, it focuses on ensuring discussions between jurisdictions before advancing regulatory proposals to determine if regulatory alignment is beneficial.

There was some interest by nongovernmental organizations and consumer groups in Canada-U.S. regulatory cooperation, but there was limited participation in discussions or concerns expressed.

Sectors involved

The first stage of the RCC was framed by economic sector but evolved to focus more appropriately on areas of regulations between similarly mandated agencies. Those agencies established bi-national technical working groups and worked with industry to identify alignment opportunities. Work plans in the following areas were developed:

PARTNERING AGENCIES	WORKPLAN AREAS
U.S. FDA (Food and Drug Administration) and Health Canada	Medical Devices Pharmaceutical and Biological Products Consumer Products Over-the-counter Products Common Electronic Submission Gateway Good Manufacturing Practices
Environmental Protection Administration (EPA) and Pesticide Management Regulatory Agency (PMRA)	Pesticides
U.S. FDA (Food and Drug Administration) and the Canadian Food Inspection Agency (CFIA)	Common Approaches to Food Safety Food Lab Recognition Criteria, Test Results and Methodologies
U.S. Occupational Safety and Health Administration (OSHA) and Health Canada (HC)	Workplace Chemicals
U.S. Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA)	Plant Health Animal Health Meat Inspection Meat Cut Nomenclature
U.S. Department of Transportation (DOT) and Transport Canada (TC)	Motor Vehicle Standards Connected Vehicles Rail Safety Aviation Regulations Transportation of Dangerous Goods Unmanned Aircraft
U.S. Coast Guard (USCG) and Transport Canada (TC)	Marine Safety (Programs) Marine Safety (Operations) Recreational Boat Manufacturing Life jackets
U.S. Environmental Protection Administration (EPA) and Environment and Climate Change Canada (ECC)	Locomotive Emissions Light Duty Trucks
U.S. Department of Energy (DOE) and Natural Resources Canada (NRCan)	Energy Efficiency Standards Alternative Fuel Use in Transportation
U.S. Pipeline and Hazardous Materials Safety Administration (PHSMA) and Natural Resources Canada (NRCan)	Explosives Classification
U.S. Environmental Protection Administration (EPA) and Environment and Climate Change Canada (ECC)	Chemicals Management
U.S. National Oceanic and Atmospheric Association (NOAA) and Department of Fisheries and Oceans Canada (DFO)	Open Cage Aquaculture

Benefits of cooperation

It is difficult to quantify the overall potential benefits of regulatory cooperation, as regulated areas are dealt with differently. Some areas are much more heavily regulated than others, and the method of regulation and related costs vary greatly. Efforts to determine benefits invariably lead to generalities, and reliable data is only available through examining individual situations and issues. From a more general and qualitative standpoint though, there are a several benefits that can be achieved for consumers, industry and regulators themselves:

CONSUMERS CAN BENEFIT FROM:

- The combined expertise of jurisdictions in addressing risk.
- A reduction in unnecessary costs incurred by business that could translate into lower cost or higher quality.
- Simultaneous availability of products in both jurisdictions (i.e. avoid delays).

INDUSTRY CAN BENEFIT FROM

- Being able to produce to common standards for both jurisdictions.
- Reduction in time to bring products to market across the jurisdictions.
- Elimination of costs related to unnecessary and duplicative requirements.

REGULATORS CAN BENEFIT FROM:

- Combined expertise in addressing risk.
- Leveraging the results and efforts of others.
- Directing any cost savings towards emerging priorities.

Other regulatory reform strategies

Regulatory reform is a recurring effort in almost all jurisdictions, involving various approaches to reducing administrative burden and improving the efficiency and effectiveness of regulatory systems.

Canada and the U.S. have adopted similar approaches over time, including administrative burden reduction projects, small-business lens development, institution of forward planning, and “one for one” or “one for two” conditions for new regulation promulgation, which are currently in place.

Similarly, provinces and states have undertaken efforts to address regulatory burden and red tape. As an example, Ontario has engaged with businesses to identify and address regulatory burden and has led sector-specific red tape exercises such as the Ontario Ministry of Agriculture's "Food and Rural Affairs' Open for Business Table".

These efforts are complementary to regulatory modernization efforts, and in many cases action in one area serves to advance the goals of the other. Regulatory reform strategies have had tangible results as individual initiatives, but none has been a “game-

changer" that served to fundamentally transform any regulatory system in a material way.

Feedback from some recent efforts such as the Red Tape Reduction Initiative in Canada and the Canada-U.S. RCC have highlighted the importance of engagement and transparency as critical elements of any future strategy. The stakeholder commentary in the *2015-16 Scorecard Report on Reducing Regulatory Red Tape* raised some important points. In particular, stakeholders cited the improved transparency that was embedded in some of the regulatory process improvements (e.g. forward planning) but stated that more consultation is needed.

It also raised the necessity that new approaches should be institutionalized; that efforts should move from a special initiative to an ongoing effort; and that engagement, consultations and discussions should be embedded into regular schedules. Finally, awareness of a new approach should be further promoted and adopted within Departments.

One of the most important lessons learned from the regulatory cooperation effort is that relying on existing practices of consultation about regulatory proposals or drafts is not adequate to generate alignment between the two countries. Canada and the U.S. have world-leading regulatory practices; they have both embedded requirements for consideration of trading partners in their regulation and rule-making policies; yet regulatory systems have not evolved in alignment.

However, current policies never anticipated regulatory cooperation with other jurisdictions to the degree now being contemplated. The U.S. enhanced their policy support of regulatory cooperation through Executive Order 13609 on international regulatory cooperation in 2012.

Above and beyond consultations during the formal rule-making processes that are 'late in the game' for regulatory cooperation to occur, early discussion between stakeholders and regulators is required to shape overall regulatory directions well in advance of any proposed changes.

Regulators can benefit from discussions with stakeholders on evolving consumer preferences, upcoming industry technology changes, and important changes in increasingly complex supply chains so that they can consider regulatory system directions over the medium and long term.

Stakeholders can benefit from an earlier view of what is being considered so that they can provide strategic input rather than having to react to individual regulatory changes, and so they have an opportunity to clarify the impact of regulatory choices at an early stage. Discussions are required well in advance of regulatory proposals taking shape in government, which is what was instituted in the annual regulatory cooperation engagement and planning commitments between Canada and the U.S..

There are a variety of tools and initiatives that can serve to advance regulatory reform. However, any effort, past or future, would be strengthened through a shift towards deeper engagement between regulators and between regulators and stakeholders.

There is an increasing complexity of areas to be regulated, and an ongoing desire to reduce unnecessary and duplicative requirements and associated costs to business and consumers. There have been lessons learned from previous efforts that signal that this is an imperative going forward. This deeper engagement can be secured through:

- Engagement between regulators and with stakeholders to discuss industry trends and changes in advance of the consideration of any regulatory proposals and to coordinate between jurisdictions.
- Establishing an annual schedule for these discussions to institutionalize the process.
- Promoting the adoption of advance discussion as an evolution in culture in government and in the stakeholder community as an imperative, given the increasing complexity of areas to regulate both technologically, as supply chains globalize and as consumer preferences and risk tolerance change.

Future regulatory cooperation

The atmosphere for regulatory cooperation is increasingly favourable. In addition to the international trade and regulatory context described above that is creating a natural imperative for greater partnership, governments remain focussed on a more streamlined regulatory environment.

The U.S. passed a specific Executive Order in 2012 on International Regulatory Cooperation, establishing a status for work plans and providing additional policy authority at the center (OIRA – Office of Information and Regulatory Affairs in the Executive Office Branch of the White House) to bring regulatory departments together on international regulatory cooperation.

Since then, the new U.S. administration has signed two additional Executive Orders (13771 & 13777) to advance regulatory reform and burden reduction. Canada is only now considering changes to its rule-making policies and expectations that commensurate changes will be made to support regulatory cooperation and alignment are high.

Most important in advancing regulatory cooperation is the regulators themselves – they need to see the efficiency and effectiveness improvements to the delivery of their health, safety and environmental protection mandates by breaking them out of their current domestic-centric focus. Seeing these opportunities through cooperation and partnership is still in a very early stage.

Stakeholders have been unwavering in their support for regulatory cooperation and for higher levels of ambition. Some work still remains to be done by government to institutionalize regulatory cooperation as an ongoing effort, however. Firm commitment to annual planning, making policy changes to entrench regulatory cooperation, and improved governance would complete the package.

SECTION THREE

Untapped Opportunities – Advancing Regulatory Cooperation in the Great Lakes

There are several avenues for provincial and state leadership and involvement in developing regulatory systems between jurisdictions. Consideration should include who is currently involved in regulating in that area, to what degree is the desired outcome being achieved through the work of others, and whether regulation is needed to the same degree and with the type of instrument currently in use.

Unilateral provincial and state changes are changes that can be made within individual jurisdictions to align to other regulations, defer to or reference other instruments or standards, deregulate, etc.

Pursuing regulatory partnership between provinces and states refers to alignment between similarly mandated Departments in sub-national jurisdictions seeking to work together where benefits to stakeholders are apparent. This can involve all or a subset of the jurisdictions within the Great Lakes Region. This can occur informally or in a more formal way between U.S. States as an Interstate Compact as per Article 1, Section 10 of the United States Constitution. Canadian provinces can be included in these compacts as associate members through memoranda of understanding that outline shared interests that align to compact.

Taking advantage of third party standards means leveraging the capacity of private organizations to establish and update standards or systems that can be referenced or recognized by provincial and state regulations.

Coordinating input to federal efforts refers to aligning views within the region and presenting opportunities and priorities to the Canadian and U.S. governments for inclusion in initiatives such as the Regulatory Cooperation Council.

Proposed issue-identification process

Advancing regulatory cooperation and alignment through greater partnership between similarly-mandated agencies in the states and provinces in the Great Lakes Region does not mean that a single regulatory system across jurisdictions is being developed. Each jurisdiction still retains its own regulatory system, but the relationship between them can include much greater recognition of the outcomes already achieved and aligning requirements to be met.

Regulatory cooperation and alignment is not generally applied; rather it is specifically applied in situations where opportunities have been identified through regulators and stakeholders. To be successful, however, regulatory cooperation should constitute a new lens through which any regulatory development is being considered. Hence the necessity arises to institutionalize an approach to continually identify opportunities, to set a process in place for regular stakeholder discussions, and to establish these as early discussions in advance of rule-making by the executive and the legislative branches of government.

These discussions are not the same as formal consultations on regulatory proposals. They are separate from the formal rule-making procedures, focussed on short, medium and long-term opportunities for greater regulatory cooperation between jurisdictions, and should include stakeholders for key elements of the discussions.

Regulators need to establish plans among themselves to align and synchronize their regulatory systems, but this process needs to be informed by stakeholders, who are uniquely positioned to identify those areas where alignment can generate benefits and to provide insights into the trends and changes in their sectors that may impact on regulatory directions and approaches.

Overall, the regulatory system becomes more integrated between jurisdictions and anticipates and adapts to the changes occurring in manufacturing and supply chains that would otherwise lead to unnecessary and duplicative requirements and costs.

Priority opportunities

An initial review of preliminary input from both government agencies and stakeholders identified the following areas where these discussions should be initiated.

AREA OF REGULATION	AREA OF OPPORTUNITY	POSSIBLE INITIATIVE	FED, STATE OR PROV
Agriculture and Food	Meat inspection	Inter-provincial shipment by provincial facilities Inspection protocols, product and packaging standards	F/P F/S/P
	Organic food standards	Differences in standards	F/S/P
	Alcoholic beverages	Personal exemptions Direct to consumer sales	P P/S
	Seeds	Registration for import and export	F/S/P
	Margarine	Differences in Quebec labeling rules and federal regulations	F/P
	Grains	Grade certifications	F
	Incident reporting	Coordination and information sharing at provincial and state level	S/P
Construction	Occupational health and safety standards	Construction safety harnesses	P
Transport	Trucking	First aid kits on trucks Truck weights and hours of service E-licenses Proof of insurance for vehicles	S/P F/S/P S/P S/P
Environment	Energy efficiency	Appliances Alignment with provinces and Canadian and U.S. federal requirements Biomass/renewable energy equipment	F/P F/P S/P
	Flame retardants	Differences in provincial and state regs	F/S/P
	Gasoline	Ethanol content	P
	Recycling	Differences in programs, blue box etc	S/P
	Hazardous waste	Movement across fed/state/prov borders	F/S/P
Consumer Products	Flushable wipes	Currently unregulated but municipalities are considering regulating.	S/P
Construction	Building codes	Electrical Permits Municipal requirements Plumbing standards	S/P S/P S/P
Marine	Vessels	Inspection Reporting Ballast water Emissions	F F F/S F/S/P

Engagement Strategy – Getting Started

Success in regulatory cooperation is premised on new processes and relationships between regulatory agencies, discussions with stakeholders specific to regulatory cooperation, and policies within government that establish regulatory cooperation as a new lens and an ongoing imperative.

At its most fundamental level, discussion is required between stakeholders and between regulators of similarly mandated agencies in different jurisdictions on opportunities for regulatory alignment and changes that can lead to benefits across sectors and supply chains.

This is a new type of discussion, and participants will need to prepare in new ways. Regulators will need to consider what they are doing and what role a partner or another jurisdiction might play, and be prepared to do things in a different way. Stakeholders will need to quantify impacts so that opportunities can be associated with tangible benefits.

A first round of discussions between similarly mandated agencies within the Great Lakes Region is an appropriate place to begin working on a regulatory cooperation work plan. Ideally, these meetings would occur in immediate proximity to each other to provide for attendance by stakeholders who have interest in more than one area.

In the case of the Canada-U.S. regulatory cooperation, the meetings have been held over 1.5 days in Washington D.C. at the Canadian embassy. The first half day was devoted to regulatory cooperation overall and the next day a series of sessions between regulators and stakeholders were held on technical work plans. The sessions should be grouped by regulatory areas and, given their strategic nature, should be led by senior regulators who have responsibility for directing their respective regulatory system.

In the federal regulatory cooperation effort, there were 14 sessions organized within the planning event between similarly mandated agencies around various areas of business such as medical devices, veterinary drugs, meat inspection, chemicals, automobile safety, rail safety etc. Most stakeholders had interest in

more than one sub-group because of the nature of their industry, and these interests were coordinated in advance such that scheduling during the 1.5 days could accommodate stakeholders attending all the sessions they identified.

There was no other practical way to ensure optimal engagement between stakeholders and departments, and the importance of having regulators from the two jurisdictions in the room with stakeholders at the same time was critical. It also served to limit both stakeholder and regulator travel.

There was no natural venue or event that would draw the broad range of stakeholders and government departments together at the same time, so dedicated RCC sessions were arranged in Washington DC at the Canadian Embassy. There is, however, an opportunity to use the Council of the Great Lakes Region's annual Great Lakes Economic Forum in the spring of each year as an opportunity to arrange these planning sessions between jurisdictions and stakeholders.

To allow for fulsome discussions, suggestions for regulatory cooperation should be solicited in advance from both regulatory agencies and stakeholders. Submissions should include the area of regulation, specific initiatives, and ideas on how to align and elaborate the potential benefit that might accrue. This latter aspect is mostly in the purview of stakeholders, who have the best idea of the tangible effect of any changes. Consideration can also be given to establishing an oversight function between jurisdictions to help advance regulatory cooperation.

Governance

Building and maintaining momentum, particularly over the first few years until new processes and behaviors become the "new normal", will rquire leadership. This leadership will need to be at a government-wide level and at a regulatory department level. In the case of the federal regulatory cooperation exercise, there was central agency leadership (Privy Council Office and White House Executive Office Branch) during the period when important progress was made. At the Departmental level, the most senior officials with responsibility for the regulatory systems were asked to work with their counterparts and agree to joint partnership statements, outlining their commitments to ongoing planning and cooperation.

Governance should exist at two levels. At the government-wide level, a Great Lakes Regulatory Cooperation Council, perhaps formed under the auspices of the Council of the Great Lakes Region (CGLR) with representatives from the implicated governments with oversight of regulatory departments, is strongly recommended. This Great Lakes RCC should include regulatory department heads so that common goals and levels of ambition are understood. It is also recommended that a small secretariat, possibly under CGLR, be formed to support the council and provide a single point of contact for stakeholders, and to maintain linkages with the various jurisdictions, including the federal government.

To initiate the development of a governance model for regulatory cooperation between jurisdictions in the Great Lakes, the following framework could be followed:

a. Identify a lead from the center of government with oversight responsibility on regulatory departments as a representative of an inter-jurisdictional committee tasked with advancing regulatory cooperation across the Great Lakes Region.
b. Develop a terms of reference, outlining the document objectives, scope and desired outcomes of the effort that could be used to socialize the approach within each jurisdiction.
c. Each jurisdiction would develop an inter-agency committee that includes the heads of regulatory, trade and industry departments to oversee the initiative and ensure that ambition and commitment is high.
d. Each Department would set up its own team, primarily focussed on stakeholder engagement for opportunity identification and workplan development, and technical working groups to advance workplan implementation with similarly mandated agencies in other jurisdictions.
e. Establish a process for input and stakeholder engagement with each of these groups.

The focus of these groups is not uniquely on their own regulations and implementation procedures, but is also to discuss how best to influence the federal regulatory cooperation workplans and strategic directions as well as regarding the Canada Free Trade Agreement and other state/provincial efforts. Input to the federal governments on a regional basis, and aligned between Canadian and U.S. agencies and stakeholders, will weigh more heavily when supported by the Great Lakes Region members than any individual submissions.

At the regulatory Department level, groups of regulatory officials from similarly-mandated agencies between jurisdictions should be formed to provide oversight for the technical working groups. As an example, Health Canada and the FDA worked closely at the Assistant Deputy Minister level with oversight of groups working on pharmaceuticals, medical devices, veterinary drugs, consumer products etc.

The importance of leadership and ownership by the regulatory department is key. These are the organizations with responsibility for the health and safety and environmental protection mandates, they are best placed to determine how to best deliver these mandates in a regulatory partnership context.

Stakeholders to engage

Stakeholder engagement is an essential element of pursuing regulatory cooperation. The Canada-U.S.

regulatory cooperation effort demonstrated that the effects of regulation and the potential benefits of alignment on individual supply chains or products are simply not fully understood by government regulators. This is not surprising given the increasingly complex and shifting environment that stakeholders need to navigate.

Stakeholders have specific viewpoints into manufacturing and supply chains, markets, and the related trends and changes that are coming in their sectors. These all translate into both opportunities and potential misalignments should they not be addressed early in considering what and how to regulate. They also have industry-specific detail on the impact of regulations, which is not apparent or available to government regulators tasked with assessing costs and benefits, or developing regulatory options.

As the case studies in this report demonstrate, the costs associated with course correction are high and entirely avoidable. Therefore, a deeper relationship with key stakeholders specific to regulatory cooperation – industry, thought-leaders, and NGOs , is the only way to better inform regulators and allow them to achieve health, safety and environmental protection outcomes in the most economical and least disruptive manner possible.

INDUSTRY

There are both multi-sectoral (e.g., general business associations and chambers of commerce) and sectoral (covering distinct sub-sectors such as auto, meat, consumer products etc.) industry associations. The multi-sectoral stakeholders will have a general interest in regulatory cooperation and what it represents as a policy and as an overall approach across regulated areas, while the sectoral will have more acute interests related to their industry sector. The multi-sectoral stakeholders occupy a space bridging between the interests of specific sectors and as thought leaders about government policy.

The industry sectoral stakeholders should be considered full partners in advancing regulatory cooperation given their role at a strategic level and in the development of ongoing workplans. Industry stakeholders will contribute at a strategic level providing insight on industry trends and changes so that regulators can adjust regulatory system directions. They will also identify alignment opportunities for inclusion in workplans covering the short and medium term and are uniquely placed to clarify benefits that could be generated through alignment. Their ongoing role through formal consultations on regulatory proposals is apart from their role in advancing regulatory cooperation.

Engagement should be open to industry associations as well as individual businesses, as they have acute interest in a stable and predictable business environment. They are also best placed to assess the specific costs associated with regulatory misalignment or differences and can bring compelling data to the discussion.

Unlike the formal consultations that occur during the rule-making process as proposals are made public, part of the engagement for regulatory cooperation should be structured and scheduled annually. This aspect will be at a strategic level and should provide opportunities for senior regulators and industry stakeholders to meet and discuss the overall regulation of the sector and upcoming changes. There will also be engagement at a technical level about specific opportunities for alignment of regulations, programs, implementation procedures, or administrative requirements.

Industry is the primary group with whom regulatory departments should develop an engagement approach to discuss technical workplan progress (once underway). Quarterly opportunities to discuss progress and any other matters is an optimal frequency.

Desired Outcome:

- Support for the overall initiative
- Ongoing participation at both the strategic and technical level
- Appreciation of their industry and proactive engagement with government

THOUGHT LEADERS AND INFLUENCERS

This group would be particularly useful in helping to introduce and socialize the concept of regulatory cooperation into the business and trade vernacular. Thought leaders are particularly helpful as ideas are taking shape and at the evolutionary stages of advancing initiatives. The dialogue is often sophisticated and, for the proponents of regulatory cooperation, it is extremely helpful in providing a forum for informed exchange and refining of approach. For the group, a forum provides an opportunity to pursue a deeper understanding of the initiative and to situate it within the area of their expertise.

Thought leaders are often the individuals to whom government committees, media, and others turn for objective opinion and advice. They are also active in publishing papers and contributing articles for magazines and trade journals. Their contributions to understanding any regulatory cooperation initiative and its goals are beneficial for all concerned.

There are no regularly occurring opportunities to engage these groups, and thought should be given about the best time to engage them and for what desired outcome. In some situations, a pre-existing group may not exist, and bringing experts and thought leaders together for a specific purpose is often required. The list below includes individuals and organizations who have demonstrated an interest in regulatory cooperation and who would be well placed to organize sessions around.

Desired Outcome:

- Recognition of the importance and benefits of the initiative
- Incorporation of the concept into their area of expertise where possible, and ongoing idea generation
- Leveraging their publications and papers to broaden and advance the understanding of the initiative

NGOs

These are special-interest groups associated with a wide range of issues (consumer, environment, welfare, rights, etc.). They should be engaged so that they understand and can provide input into the initiative and bring any issues they have, related to their area of interest, to light. When it comes to regulatory cooperation or greater partnership between jurisdictions, there are some predictable and legitimate concerns that will likely come to mind and that should be discussed. These include loss of sovereignty, race to the bottom, unexamined adoption of another's jurisdictional standards, a move to a single regulatory system administered outside of one's control, etc.

In addition, regulatory cooperation can generate opportunities for both business and consumers. Consumers can benefit from greater product availability, simultaneous availability of products in markets, lower costs, increased scientific scrutiny through closer work between jurisdictions, etc.

These issues are important to address at the outset, and effort should be made to engage these groups at an early opportunity.

Desired Outcome:

- Appreciation of the benefits of the initiative
- Factual understanding of what the initiative is and isn't

Levels of engagement

There are two distinct levels of engagement to consider. At one level, there is common messaging regarding the overall initiative and its aggregate impact and benefits. At the other level, there are specific initiatives in technical workplans that are of acute interest to sectoral stakeholder groups and special-interest groups.

COMMUNICATIONS AND OUTREACH

Continuity of messaging is important, particularly when several jurisdictions will be potentially involved in the effort. If possible, key individuals who have a leadership role in advancing the initiative and responsibility for making course corrections to keep forward momentum should undertake the first level of engagement regarding the overall initiative. Whether this group is in a central office, a virtual team, or designated individuals within jurisdictions that can work together to develop and deliver consistent messaging, it should be a small group tasked with proactively engaging the key stakeholder groups on the overall initiative.

TECHNICAL WORK GROUPS AND WORKPLANS

The technical level of engagement should be led in each department, in coordination with their similarly mandated agencies in other jurisdictions, by the most senior technical officials responsible for the regulatory system. Stakeholders expect regular discussions on opportunities and workplan progress, so a formal engagement plan should be developed and messaging should be aligned between jurisdictions.

Strategic and more senior-level discussions should occur annually. These provide an opportunity for stakeholders and senior regulatory staff responsible for the overall regulatory system to discuss industry trends and changes that may impact on regulatory system directions and policies. This is the opportunity to consider where and how to regulate over the next 3-5 years. It provides context for further discussions between regulators in the various jurisdictions on how to achieve regulatory outcomes together in a changing environment. More technical discussions are also required on short term opportunities and to discuss workplan items already underway. A sample agenda for these discussions is attached in Appendix B.

Once opportunities have been identified and discussions held to elaborate and deepen the understanding of the issue, technical working groups between regulators need to be established. These are co-chaired between the implicated jurisdictions and involve technical staff with subject-matter knowledge. Workplans should be developed that outline a path forward with tangible deliverables. Even though the work planning process is annual, many issues can take more than a year to resolve, so the reach of the workplan will often extend past the one-year period.

Discussions between regulators should also focus on why the misalignment took place. It may be necessary to work on aligning not just the regulation itself, but some of the other elements within the regulatory system. When considering where processes might align internally, the following is illustrative. During the federal regulatory cooperation exercise, almost all issues fell within the following four categories of work. An example of the types of regulator-to-regulator routine work that might need to be addressed is also included.

- Common standards and tests:
  - Joint standards development using combined data
  - Joint testing methodology development
  - Certification procedures and acceptance
  - Jointly approved certification bodies
- Product approvals and reviews:
  - Single-point application process between jurisdictions
  - Joint risk assessment and combined data sets
  - Single-approval process for implicated jurisdictions
  - Transparency in sovereign final decisions

- Managing third party import risk:
  - Common inspection procedures on products or facilities
  - Jointly recognized inspection and certification
  - Common single-enforcement program
  - Common risk-assessment and interdiction program
- Leveraging the outcomes achieved in the other jurisdictions:
  - Common risk-assessment, inspection program and procedures to modernize and adjust combined data together
  - Joint inspection program: eliminate need for product re-testing

While much of this category of work is preparatory or "behind the scenes", it is critical for preparing the ground for regulatory cooperation, and is often a pre-requisite for an ambitious workplan between jurisdictions. Consequently, it is recommended that this "behind the scenes" work also be included in workplans as it demonstrates commitment as well as the level of effort required to open the doors for further alignment in the general area, laying a foundation for more facilitated cooperation in the future. Regulatory systems have been developed as independent, standalone systems without the necessary open doors or bridges between jurisdictions. It took decades to build these systems, and it will take some time and effort to modify them to operate in the context of collective regulatory systems striving to achieve the same outcomes.

	FIRST 6 MONTHS	6 – 12 MONTHS	12 – 18 MONTHS
Desired Strategic Outcome	Reg coop approach has been refined and initiative is understood, supported, and being planned for by Governments and Stakeholders Benefits are understood by all parties and unwarranted concerns avoided Governance and planning cycle and approach is supported	Planning cycle is agreed to and embraced by government Departments and stakeholders – and has been launched. Ambition high Planning is underway – stakeholders are working together to provide common input, government is working together on initial opportunities – expectations well managed	Work-plans are robust and complete and have been made public across all sectors. Departments and stakeholders are comfortable with their role in both the strategic and technical planning process – new processes are being embedded in Departmental practices Oversight mechanisms have been successful and adjustments underway for the next cycle
Key Messages	New initiative to benefit business and consumers being undertaken – developed in consideration of regional needs and lessons learned from other government efforts Opportunity for regulators to work with counterparts, deliver mandate and contribute to the economy Planning will commence over the next 6 months and an initial action plan made public shortly afterwards	Planning preparations are underway, governments have met and are considering opportunities, stakeholders are preparing strategic input and short-term opportunities This is the first year and not everything will be resolved – important focus is on installing processes that will avoid misalignment in the future – this is hard to measure but of highest importance – new processes represent success.	The initial work-plan has been developed. Most important in this exercise has been the use of new processes between government and stakeholders and between governments. This exercise will result in benefits to stakeholders – business and consumers alike and governments will be more efficient and effective in delivering their health, safety and environmental protection mandates
Governance	First meeting of inter-government Council has taken place to discuss planning process and confirm commitment Similarly-mandated Departments between various governments have met to discuss planning and initial opportunities	Government stakeholder (G-S) conference to launch formal planning has taken place. Both a general session on the initiative and sector specific technical meetings have taken place in one setting Council meeting on progress has taken place	Council meeting is held to discuss lessons learned and make changes for the next year.
Engagement	Meetings with thought leaders, multi-sectoral organizations and special interest groups complete	Pre-meetings with sectoral groups to explain planning process and their role complete. Departments have completed and shared engagement strategy for work-plan development with stakeholders	Departments are executing their engagement plans with Departments on work-plan implementation and other issues as they arise. Meetings held with multi-sectoral stakeholders, thought leaders and special interest groups to discuss progress and ideas for improvement
Planning	Preparations are complete – process to solicit input ready to go, planning cycle outlined	Request for areas of opportunity for work planning process was sent and input received for the G-S conference Planning cycle is public	Planning cycle is refined and planning for the G-S conference is underway. Workplan progress is discussed with stakeholders as per the department led technical workplan engagement strategy

Conclusion

"Unnecessary regulatory differences and duplicative actions hinder cross-border trade and investment, and ultimately impose a cost on our citizens, businesses and economies. Given the integrated nature of our economies, greater alignment and better mutual reliance in our regulatory approaches would lead to lower costs for consumers and businesses, create more efficient supply chains, increase trade and investment, generate new export opportunities, and create jobs on both sides of the border."

– Canada-U.S. Regulatory Cooperation Council

This paper is intended as a basic road map and rationale for regulatory cooperation. Without question, operating regulatory systems independently without consideration of the effect of layering requirements on stakeholders has created unnecessary cost and administrative burden for business and is impacting consumers. The good news is that the North American regulatory environment is populated with highly skilled regulators and world-class systems. These provide an opportunity for greater rationalization and streamlining between jurisdictions, all of which have similar outcomes in mind.

The process contained in this report will suffice to get a discussion started. Stakeholders who can provide a practical view of the increasingly complex manufacturing and trade environment for regulators will inform the discussion. Awareness will build, processes will change, behaviors will be adjusted based on new processes, and a new culture will form.

Regulatory cooperation is the next arena of discussion in the trade world. The Great Lakes Region has an opportunity to lead the way at the sub-national level, and allow for benefits to accrue to business, consumers and to regulators themselves. There is no single right model for regulatory cooperation, but these are the right first steps, and getting started will allow for the right model to take shape for the region over time. It can proceed in the Great Lakes Region, as it did under the RCC, without compromising consumer trust, public health, and environmental protections that citizens on both sides of the border expect.

Appendix A – Proposed Stakeholders

U.S. STATE CONTACTS	
Pennsylvania Department of General Services	The Honorable Curt Topper (Secretary) 515 North Office Building, Harrisburg, PA 17125
Lieutenant Governor of Ohio	The Honorable Mary Taylor 77 S High St, 30th Floor, Columbus, OH 43215
Michigan Office of Performance and Transformation	Jeff Bankowski (Executive Director) George W. Romney Building, 8th Floor 111, Capitol Avenue, Lansing, MI 48913
Indiana Office of Management and Budget	Micah Vincent (Director) 200 West Washington Street, Room 212 Indianapolis, IN 46204
Wisconsin Commission on Government Reform, Efficiency, and Performance	The Honorable Scott Neitzel (Secretary) Wisconsin Department of Administration PO Box 7864, Madison, WI 53707
Office of the Governor, Minnesota	Kimberly Slay Holmes (General Counsel and Assistant Chief of Chief) Suite 130, 75 Rev Dr Martin Luther King Jr Blvd. St Paul, MN 551551611
New York State Division of the Budget	Robert Mujica (Director) State Capitol, Room 335, Albany, NY 12247

CANADIAN PROVINCE CONTACTS	
Quebec Ministry Ministry for Small and Medium Enterprises, Regulatory Streamlining and Regional Economic Development	Jocelin Dumas (Sous-ministre) Ministère de l'Économie, de la Science et de l'Innovation 710, place D'Youville, 6e étage Québec, QC G1R 4Y4
Ontario Minister of Economic Development and Growth	Giles Gherson (Deputy Minister) 7th Floor, 56 Wellesley Street West, Toronto, ON M7A 2E7

CANADIAN ORGANIZATIONS – MULTISECTORAL	
Importers and Exporters Association	Joy Nott (President) Keith Mussar (VP Reg. Affairs)
Canadian Chamber of Commerce	Warren Everson (Sr. VP Policy)
Business Council of Canada	Susan Scotti (Exec. VP)
Canadian Federation of Independent Business	Corinne Pohlmann (VP, National Affairs)
Canadian Manufacturers and Exporters	Pres. Dennis Darby Mathew Wilson (Sr. VP)
American Chamber of Commerce in Canada	David Olsen (Toronto-GTA Chapter Chair)
Ontario Chamber of Commerce	Rocco Rossi (President and CEO)

U.S. ORGANIZATIONS – MULTISECTORAL	
U.S. Chamber of Commerce	Sean Heather (Exec Director, Global Regulatory Cooperation)
Canadian American Business Council	Maryscott Greenwood (President)
National Association of Manufacturing	Jay Timmons (President)
National Federation of Independent Business	Juanita D. Duggan (President)
The Business Council of New York	Heather C. Briccetti (President)
Pennsylvania Chamber of Business and Industry	Gene Barr (President)
Ohio Chamber of Commerce	Andrew E. Doehrel (President)
Michigan Chamber of Commerce	Richard K. Studley (President)
Indiana Chamber	Kevin Brinegar (President)
Illinois Chamber	Todd Maisch (President)
Wisconsin Manufacturers & Commerce	Kurt Bauer (President)
Minnesota Chamber of Commerce	Doug Loon (President)

CANADIAN ORGANIZATIONS – SECTORAL	
Consumer Health Products Canada	Karen Proud (President)
Retail Council of Canada	Jason McClinton (VP Grocery and Reg. Affairs)
Canadian Meat Council	Chris White (President)
Consumer Electronics Marketers of Canada	Susan Winter (VP)
Canadian Electricity Association	Sergio Marchi (President)
Canadian Cosmetic, Toiletry and Fragrance Association	Darren Praznik (President)
Canadian Motor Vehicle Association	Mark Nantais (President)
Forest Products Association of Canada	Derek Nighbor (President)
CSA Group	Doug Morton (Dir Govt. Relations and Standards)
Canadian Institute of Plumbing and Heating	Ralph Suppa (President)
Canadian Trucking Alliance	Steve Laskowski (President)
Food and Consumer Products Canada	Carla Ventin (VP Fed. Govt. Affairs)
Canadian Energy Efficiency Alliance	Elizabeth McDonald (President)
Heating, Refrigeration and Air Conditioning Institute of Canada	Martin Luymes (Director, Programs and Relations)
Rx&D	Walter Robinson (VP Govt. Affairs)

U.S. ORGANIZATIONS – SECTORAL	
American Automotive Policy Council	Matt Blunt (President)
American Trucking Associations	Margaret Irwin (Director – cross border)
National Marine Manufacturers Association	T. Nicole Vasilaros (Director – Reg. and Legal Affairs)
American Boat and Yacht Council	Brian Goodwin (Director – Technical)
Association of American Railroads	John T. Gray (Sr. VP)
Association of Home Appliance Manufacturers	Robert D McArver (VP Policy and Govt. Relations) Pres Joseph McGuire
International Wood Products Association	Brent McClendon (Exec VP)

U.S. STATE OR REGIONAL ORGANIZATIONS – SECTORAL	
Lake Carriers Association (Great Lakes)	James Weakley (President)
Chamber of Marine Commerce	Bruce Burrows (President)

THOUGHT LEADERS / THINK TANKS	
Wilson Center, Washington DC, Canada Institute	Laura Dawson (Director)
Dickinson-Wright, Columbus Ohio	Dan Ujczo (Cross Border Business Development Director)
Queens University, Queens Institute on Trade Policy	Robert Wolfe (Director)
Western University, Ivey Business School, Lawrence Center	Leslie Coates (Managing Director)

NGO'S / SPECIAL INTEREST GROUPS	
Consumers Association of Canada	Bruce Cran (President)
Canadian Federation of Independent Business	Dan Kelly (President)

Appendix B – Sample Agenda

To be preceded by advance solicitation of regulatory cooperation opportunities from regulatory agencies and stakeholders

1. **Regulator to Regulator Preliminary Discussion**
   a. Current regulatory plans and initiatives
      — Proposals next 12 months
   b. Medium and long term regulatory directions
      — Anticipated challenges
      — Regulatory models and approaches

2. **Regulator – Stakeholder Discussions**
   a. Stakeholders lead
      — Short term opportunities
      — Trends in the sector that may influence the regulatory system
         1. Technological change
         2. Supply chain evolution
         3. Longer term trends
         4. Consumer trends
   b. Regulator/stakeholder discussion on short term opportunities and potential impact on medium and long term regulatory system directions

3. **Regulator to Regulator Planning**
   a. Development of a work plan
   b. Establishment of an implementation process between jurisdictions
   c. Engagement plan with stakeholders
   d. Communications plan

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