

# Regulatory Cooperation and Food Safety under NAFTA 2.0

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## **CANADA-US REGULATORY COOPERATION: PROGRESS TO DATE AND LEVERAGING NAFTA 2.0**

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# Outline

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- **Context**
  - Traditional trade agreement approaches
  - Evolution of trade and manufacturing – new reality for regulators
- **Overview of Canada-US Regulatory Cooperation**
  - Where regulatory cooperation best applies
  - Areas of opportunity between regulators
- **Next steps to secure success**
- **NAFTA**
  - How can it set the stage for deeper cooperation?
  - Specific inclusions that would help
- **Why these changes are important**

# Previous / Traditional Approaches

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- WTO-based rights and obligations
- National government and country to country focus
- Many sub-disciplines and concepts
  - TBT, SPS, national treatment etc.
- Dispute settlement and recourse
- Highly effective and successful in addressing tariffs, basic market access
- Changed the trade dynamic – now at a new starting point

# Evolution of Trade and Manufacturing

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## New reality for Regulatory Systems:

- Integrated supply chains are predominant
- Global products are a reality
- Regulatory systems are following but not keeping pace
  - Regulators paradigm remains country-centric; the traditional trade view
- Manufacturing standardization and facilitated market access is hindered
- Domestic regulatory system effectiveness in achieving outcomes is increasingly challenged

# Regulatory Cooperation Overview

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- Canada-US as initial priority – driven by Leaders commitment
- Recognized the integration of the Canada-US economy
  - Manufacturing, supply chains and consumer markets
- Existence of 2 independent regulatory systems on the same value chain and firms, creating unnecessary costs and requirements impacting industry, consumers, government
- First 5 years: 2011-16
  - From a concept, to a pilot, to 100's of initiatives
  - Introduction of a new partnership model and planning cycle
- At its core, signalled a new language and type of discussion between Canada-US Regulatory Agencies

# Regulatory Cooperation Overview [2]

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## Key findings:

- Misalignment costs are not due to regulation itself, but the procedures and requirements associated with them
- Regulatory Departments have a low level of awareness of impact on industry costs
- One way trade irritants don't fit, need willingness on both sides to change something
- Stakeholders have an important role
  - Quantifying impacts/benefits
  - Providing input on industry trends to guide regulatory system directions

# Regulatory Cooperation Overview [3]

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## Key findings cont'd:

- Enormous amount of opportunity, but:
  - Regulators need to see they can deliver mandate more efficiently and effectively through alignment and partnership
  - Effort needs to be warranted – benefits need to be apparent to spur action
- Culture change needs to be supported by policy, leadership
  - New processes > new behaviors > new culture

## Next steps:

- Complete the institutionalization between Canada and the US and further evolve regulatory partnerships

# Where Regulatory Cooperation Best Applies

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## UPSTREAM

Manufacturing & Supply Chains



## DOWNSTREAM

Products into Markets

- Where market access already exists
  - Trade irritants (TBT, SPS) or disputes have been addressed
- Where supply chains are integrated
  - Cross border manufacturing or common sourcing
- Where markets are integrated
  - Similar products offered and regulated by similarly mandated agencies
  - From domestic or foreign sources
- Where consumers have similar preferences
- Where regulators have similar approaches and risk tolerance

# Areas of Opportunity Between Regulators

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All initiatives fit into 4 categories:

## 1. Common Standards and Tests

- Joint standards development – using combined data
- Joint testing methodology development
- Single certification for both markets
- Jointly approved certification bodies

## 2. Product Approvals and Reviews

- Single point application process for both markets
- Joint **risk assessment**/combined data sets
- Single approval for both markets

# Areas of Opportunity Between Regulators [2]

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## 3. Managing 3rd Party Import Risk

- Common procedures at perimeter and foreign sites
- Jointly recognized inspection/certification
- Common single enforcement program applied once for both markets
- Enforcement for both markets at Point of Entry (not border)
- Common **risk assessment** and interdiction program

## 4. Leveraging Outcomes Achieved in the Other Jurisdiction

- Common **risk assessment**, inspection program and procedures – modernize and adjust together – using combined data
- Joint management of inspection program – eliminate product re-testing
- Plant and Animal Health – jointly manage evolving pest and disease risk due to climate and other factors based on a shared territory and zones therein – away from political boundaries

# Next Steps to Secure Success

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- Make Regulatory Policy Changes – GRP'S/Regulatory Coherence
  - Build on first generation US executive order – special consideration for regulatory cooperation initiatives that would include:
    - ✦ Use of combined data for cost benefit assessment
    - ✦ Allow for Canada-US (OIRA-RAS and Regulator to Regulator) confidential dialogue in final regulation adjustments
    - ✦ Enhance analysis of implementation procedures that would misalign or cause duplicative requirements
  - Require departmental development of internal regulatory cooperation strategies (what, when, with whom)
    - ✦ Guide work plan development as well as forward regulatory plans

# Next Steps to Secure Success [2]

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- **Enhance Governance**

- Reinstitute a Secretariat led Council to include Regulatory Department Heads
- Establish senior/political binational oversight
- Institutionalize Annual planning
- Commit to and implement a regular, predictable annual cycle
- Formalize the role of stakeholders in short, medium and long term planning
- Provide formal procedures for stakeholders to identify regulatory cooperation opportunities or issues throughout the year to Departments, Secretariat/Council, Oversight body

- **Further Regulatory Department ambition and leadership**

- Enhance analysis to better understand industry, consumer and departmental benefits of specific opportunities
- Re-vector country-centric mindset to one of regional regulatory partnership where common outcomes are desired both **upstream** and **downstream**

# NAFTA – How it can Set the Stage for Deeper Regulatory Cooperation

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## Permission, Opportunity, Aspiration, Expectation

- Signal a new stage of evolution for relationships between regulatory systems to benefit the region
- Set regulatory cooperation as a requirement where benefits are apparent
  - But unlike traditional country to country approaches – opportunities follow specific supply chains, products and their markets
  - Workplans can include non-signatories / don't require all signatories
- Provide for
  - Lead role of Regulatory Departments
  - Role and process for stakeholder involvement
  - Governance structures
- Commit to an annual planning cycle
- Set expectation for new partnerships between regulatory Departments
  - Joint efforts and more formal organization around routine activities
  - Sovereignty not affected, final decisions are still internal
  - Joint work using common approaches and combined data for single conclusions

# NAFTA – Specific Inclusions That Would Help

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## Good Regulatory Practices/ Regulatory Coherence Section

- Establish regulatory cooperation as lens to assess proposals
  - More acute focus than “international trading partner considerations”
- Establish proposals from joint regulatory cooperation workplans for special consideration
  - Cost-benefit to include an aligned result in analysis
  - Importance of including combined implementation costs in assessments

## Regulatory Cooperation Section

- Governance
  - Establish senior/political bi-national oversight body
  - Establish a Secretariat led Council that would include Regulatory Department Heads
  - Institutionalize Annual planning

# NAFTA – Specific Inclusions that Would Help [2]

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## Regulatory Cooperation Section (cont'd)

- Planning and Opportunity Identification
  - Commit to an annual work-planning cycle
  - Establish Regulatory Departments as the lead
  - Formalize the role of stakeholders during the planning cycle
  - Provide formal procedures for stakeholders to identify regulatory cooperation issues to Departments, Secretariat/Council, Oversight body at anytime
  - Recognize that work plans can be established between subsets of signatories and can include countries that are not signatories
- Nature of Cooperation
  - Set expectation/scope for new mechanisms between regulators to achieve deeper cooperation/partnership

# NAFTA – TBT/SPS Game-Changer

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## First the rational:

- NAFTA region is a contiguous territory - unique situation and opportunity
- Can move beyond duplicative country to country measures especially where common consumer markets and preferences exist and where manufacturing/supply chains are similar or integrated
  - Focus on addressing risk to consumers once, through the same measures
  - Focus on the supply chain risk, not the fact it crosses a border
- In these situations – opportunity to address plant, animal, food risk jointly
  - Implement common regional requirements and eliminate cross-border generated measures
  - Address risk at the perimeter once and eliminate cross-border generated measures

# NAFTA – TBT/SPS Game-Changer [2]

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- These requirements can be international standards, regionally developed, or be commonly adopted from third parties – and implementation procedures need to be common
  - Once recognized by the regulatory departments, implemented and jointly approved conformity assessment is in place (through a government or non-government competent authority) that it constitutes equivalence between the countries for that supply chain or product – no other requirements apply.
- Nature of the inclusions:
  - Recognize that **specific** opportunities exist as afforded by a contiguous territory, our integrated manufacturing and common risk tolerance
  - Promote the use of jointly developed common requirements and programs that implemented once, serve to satisfy the health and safety, SPS/TBT requirements for the other country(s)
  - Recognize that third party specialized systems and accredited third party conformity assessment bodies can be an alternative to traditionally developed and delivered programs

# Why Are These Changes Important?

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## The Challenge:

- Trend continues toward global mfg, supply chains, global products
- Country-centric regulatory systems reach is limited while need for reach is increasing
- Specialized knowledge requirements are increasing
- Manufacturing/supply chains increasingly complex, and attention/oversight critical
- Reliance on most countries to implement credible national regulatory systems is unrealistic and unnecessary
- Applying requirements in the Canada-US context, with two highly evolved regulatory systems, is habit and an unnecessary use of resources
- Our regulatory systems are decreasing in ability to achieve health and safety mandates in a global environment
- The country to country approach is less relevant than ever

# Why These Changes Are Important

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## The Opportunity of NAFTA

- **Evolution**
  - Outline aspirations/nature of a new type of regulatory partnership
  - Shift dialogue from what we are doing to each, to what we can do together for mutual benefit
- **Efficiency**
  - Provide for new mechanisms to move away from duplicative routine activities e.g. Risk Assessment: starting with food safety that as a model is equally warranted in consumer products, pharma, plant and animal health, auto safety, medical devices, etc.
  - Provide for shared oversight of supply chains in other countries and products manufactured elsewhere
- **Effectiveness**
  - Use of other systems and experts to achieve mandates