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Canada



Regulatory Cooperation: Lessons Learned from the North American Experience

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Overview

- 1) Changing context for regulatory systems and regulatory cooperation
- 2) Experience from the Canada-US Regulatory Cooperation Council
- 3) Six broad lessons for regulatory cooperation

Changing context of regulatory systems

25-30 years ago	Now
Few international bodies with limited impact on domestic systems.	Broad range of international and regional organizations and obligations impacting on domestic systems.
Largely domestic health and safety drivers.	Globalization and North American manufacturing and production integration has greatly reduced any 'domestic' rationale or premise.
Regulations very prescriptive. Limited industry based voluntary standards or systems.	Regulations more performance and outcomes-based. Wide range of private sector standards and manufacturer and retailer requirements.
Stakeholders organizations largely focussed on domestic interests.	Industry associations engaged internationally – sophistication has steadily increased.
Few free trade agreements and the WTO was still being discussed (1995).	Multiplicity of bilateral and plurilateral agreements, each with regulatory commitments.

New Mindset for Regulators

- Understand the economic impact of regulations
- Be aware of the international context of regulation-making
- Understand the regulatory continuum – from policy development to compliance

Canada-US RCC – Initial Action Plan (2011-14)

- 29 specific initiatives for greater regulatory alignment:
 - agriculture & food (10 items)
 - transport (10)
 - health & consumer products (4)
 - the environment (3)
 - cross-cutting issues (2)
- Each initiative an opportunity to resolve existing misalignments while avoid unnecessary regulatory differences in the futures
- Governance:
 - 12 bilateral working groups each responsible for implementing detailed work plans and consulting sector-based stakeholders
 - Overall coordination by central agencies: PCO and OIRA (OMB) in US

Initial RCC Action Plan Progress

- Successful overall – proof of concept is clear, dialogue on cooperation now prominent
- Concrete results in several sectors; e.g.,
 - ✓ Common electronic gateway for drug reviews
 - ✓ Simultaneous vet drug reviews and approvals
 - ✓ Agreement on animal disease zoning
- Evolution of thought – focus on what institutionalized cooperation might look like
- Central agency relationship (PCO and OMB-OIRA) strong and like-minded
- Stakeholder engagement and sense of opportunity increased

Canada-US RCC – Forward Plan (2014-)

- A Blueprint for Department-Level Regulatory Partnerships
 - new processes to be put in place to generate opportunities for Departments to align their work where benefits are anticipated
 - new roles for both regulators and stakeholders in these new processes
- Department to Department Commitments in Regulatory Sectors
 - a starting point to generate tangible deliverables as process work proceeds
- Cross-cutting Issues through Secretariat Leadership
 - a central agency focus address systemic issues and make changes to facilitate deeper cooperation
 - consideration of how to secure this between the countries moving forward

Lessons Learned - Canada-US RCC (1)

- Issue-based Action Plan good place to start in understanding systemic challenges to regulatory cooperation
- Regulators must lead the way to create and sustain changes
 - although require “top-down” permission
- Transparency around initiatives and meaningful stakeholder engagement are critical to maintain momentum

Lessons Learned - Canada-US RCC (2)

- Not just about aligning regulations but securing collaboration *across* several aspects of our regulatory systems
- Four key areas where regulatory cooperation can deliver significant benefits:
 - 1) Cooperation in product reviews and approval**
 - Collaborate on aligning submissions, analysis, and approval processes
 - 2) Cooperation in regulatory system reliance**
 - Reduce and eliminate duplicative requirements by recognizing success of each others' work
 - 3) Cooperation in regulatory standard-setting**
 - Partner on regulatory standards development, conformance (i.e., testing), and implementation / enforcement
 - 4) Cooperation in managing import risk at the perimeter**
 - Move border activity to the external perimeter and collaborate on efforts abroad

Six Lessons Learned on Regulatory Cooperation

#1 Effective regulatory cooperation
needs to begin at the earliest points in
the regulatory continuum

Six Lessons Learned on Regulatory Cooperation

#2 “Trust building” as a critical investment in advancing the goal of regulatory alignment

Six Lessons Learned on Regulatory Cooperation

**#3 Importance of achieving political
and senior-level buy-in**

Six Lessons Learned on Regulatory Cooperation

**#4 Harnessing strong stakeholder
support for regulatory cooperation**

Six Lessons Learned on Regulatory Cooperation

#5 Achieving a balance between the
“formal” and “informal” dimensions of
regulatory cooperation

Six Lessons Learned on Regulatory Cooperation

#6 Need to achieve mutual “wins”