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

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