Proactive Governance of Emerging Technologies : International Regulatory Cooperation

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uOttawa

ISSP

The RCC

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Prime Minister Stephen Harper and United States President Barack Obama announce the creation of the Canada-United States Regulatory Cooperation Council (RCC) to better align the two countries' regulatory approaches, where possible.

RCC & Emerging Tech

- The RCC does <u>not</u> focus on emerging technologies

  – (except for a single nanotechnology project)

- Nevertheless, commissions: **Model Framework for Canada-US Bilateral Collaboration in the Regulation of Emerging Technologies**

Life-Cycle Concept

- *Pre-Regulatory Policy Development; Early Risk Identification*

- *Joint Regulatory Agenda Setting and Work Planning*

- *Common Submission Requirements*

- *Coordinated Review Procedures and Product Requirements*

- *Coordinated Compliance and Enforcement Programs*

- *Post-Regulatory Alignment, Collaboration and Agreement*

Methods

- In-depth semi-structured Interviews

- Information organized into "life-cycle"

- Format: checklist with illustrative examples

PROACTIVE INTERNATIONAL REGULATORY COOPERATION FOR GOVERNANCE OF EMERGING TECHNOLOGIES

Marc A. Saner and Gary E. Marchant·

ABSTRACT: This article provides a systematic checklist to guide proactive bilateral and international regulatory cooperation (in the sense of "alignment" or "harmonization") in the context of emerging technologies. The article is structured along a life-cycle starting with preregulatory activities and ending with postregulatory processes. The background research is based on a series of interviews with American and Canadian experts carried out in late 2013 as well as studies of previous international regulatory alignment examples. Our aim is to inform the regulatory debate on how to best develop proactively aligned regulatory programs for emerging technologies in bilateral (e.g., United States-Canada) and international contexts.

Commerce and technology are increasingly global.[1] As the transnational flow of goods grows, government regulators seek to coordinate regulatory responses to many different problems, including oversight of emerging technologies. Yet, the debate over harmonized regulations and globalized trade remains controversial. Critics fear a migration to the "lowest common de-

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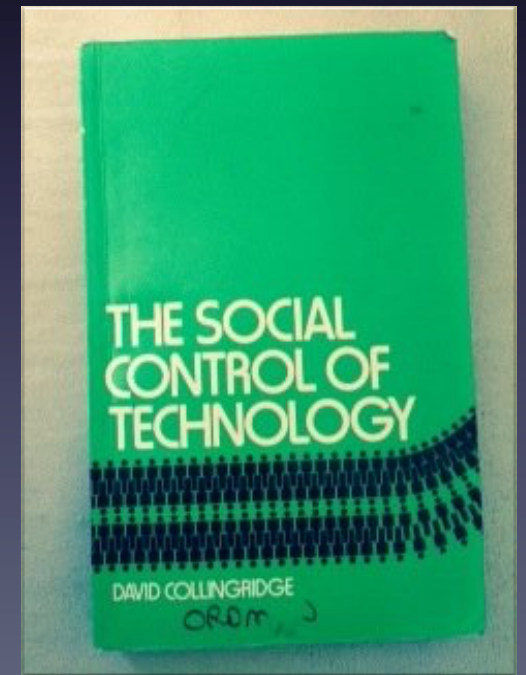
Memento: 2 Key Obstacles

1. Technology Diffusion as a Ideological Divide

  – Diffusion = enables <u>innovation</u>

  – Diffusion = prevents <u>regulation</u>

2. The Collingridge Dilemma

  – <u>First</u>: Information deficit

  – <u>Then</u>: Power deficit

Interviewees

- Andrew Atkinson (Health; Canada)

- Robert Crawhall (Consultant; former Président of NanoQuébec, Canada)

- Nicole Davidson (Environment Canada)

- Bruce Doern (University of Exeter, United Kingdom)

- Terry Medley (Dupont; formerly Department of Agriculture, United States)

- Jeff Morris (Environmental Protection Agency, United States)

- David Rejeski (Woodrow Wilson International Center for Scholars, United States)

- Treye Thomas (Consumer Safety Protection Commission, United States)

- Sally Tinkle (Science and Technology Policy Institute)

- Clive Willis (Chair, ISO Technical Committee on Nanotechnologies)

[no attributions]

Results

- "18 Priority Targets for Regulatory Alignment"

- Clustered early in the life-cycle (Collingridge …)

- This talk: quick survey, then 4 selected issues

Stage 1: Pre-regulatory Policy Development; Early Risk Identification

1

- *Engage Upstream*

- *Develop Shared Working Definitions, Test Protocols and Standards*

- *Engage Bilateral or Multilateral Senior Staff Formally and Regularly*

Stage 1: Pre-regulatory Policy Development; Early Risk Identification

1

- *Conduct Joint Technology Assessment & Regulatory Foresight Exercises*

- *Develop Common Statement of Policy Principles*

- *Build Joint Regulatory Capacity Alongside Innovation Capacity*

Stage 2: Joint Regulatory Agenda Setting and Work Planning

2

- *Determine Scope for Stakeholder Role*

- *Plan for Joint Policy Development, Regulatory Change & Adaptation*

- *Select Priority Products and Processes for Pilot Projects*

Stage 2: Joint Regulatory Agenda Setting and Work Planning

2

- *Align Domestically to Better Align Transnationally*

- *Address Multilateral and International Issues in a Bilateral Context*

Stage 3: Common Submission Requirements

3

- *Develop Data Sharing Protocols*

- *Mutual Data Reporting and Acceptance*

- *Focus on Information Technology and Knowledge Management*

Stage 4: Coordinated Review Procedures and Product Requirements

4

- *Identify Opportunities for*

    – *Joint Pre-market Risk Assessment and Regulation*

    – *Joint Post-market Risk Assessment and Regulation*

Stages 5 & 6: Compliance and Post-regulatory coordination

- *Compliance: Coordinated Compliance and Enforcement Programs*

5

- *Post-regulatory: Find Candidates for Mutual Recognition and Equivalence Agreements*

6

My Fantastic 4 (instead of Top 10)

- Resources

- Process

- People

- Structures

Resources

Proactive

ELSI Investment

Process

Formal Coordination of

Innovation & Regulatory Strategies

People

Let Regulators, Experts Meet Bilaterally

(relationships do matter)

Structures

Bilateral

Regulatory Coordination Facility

for Emerging Technologies

(Bilateral Office / Council for S&T Assessment)

Thank you!

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