International Regulatory Cooperation

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Good Regulatory Practices – An International Frame

OECD’s Recommendation of the Council on Regulatory Policy and Governance (2012) are the most advanced international guidelines and principles to be implemented by OECD member countries on regulatory quality and performance.

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<td>1.</td>
<td>Commit to whole-of-government policy for regulatory quality</td>
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<td>Develop a consistent policy covering the role of regulatory agencies</td>
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<td>Promote regulatory coherence through coordination mechanisms between all levels of government</td>
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The Canadian Context: Cabinet Directive on Regulation

Canada’s federal regulatory policy, the Cabinet Directive on Regulation (CDR), sets out the Government of Canada’s expectations and requirements in the development, management, and review of federal regulations.

During all stages of the regulatory life-cycle, regulators must seek opportunities to:

• Engage stakeholders, including Indigenous peoples

• Pursue regulatory cooperation and regulatory alignment, where appropriate

• Coordinate with all levels of government to minimize cumulative and unintended impacts on Canadians, business, and the economy

Departments and agencies are to assess opportunities for cooperation with other jurisdictions, domestically and internationally, on regulations and associated regulatory activities. This includes examining alignment of regulatory approaches and outcomes with key trading partners.

What is International Regulatory Cooperation (IRC)?

Unnecessary regulatory differences between Canada and its key trading partners can add significant costs for industry and consumers.

Regulatory cooperation can reduce or eliminate these differences, reducing costs to industry, consumers, and regulators, and increasing consumer choice.

**REGULATORY COOPERATION**

- A process to find efficiencies and reduce unnecessary regulatory differences
- Applies to full lifecycle of regulatory activities, including inspections, certification, standards, product and testing approvals
- Maintains or advances high standards of public health and safety and environmental protection
- Considered throughout the regulatory development process (i.e., policy development and consultation, regulatory impact analysis, submission, and approval stages)
Categories of IRC Mechanisms

- **Integration/harmonization through supranational institutions**
  - e.g. EU Institutions (EMA)

- **Specific negotiated agreements (treaties, conventions)**
  - e.g. Montreal Protocol Ozone

- **Regulatory partnerships between countries**
  - e.g. Canada-U.S. Regulatory Cooperation Council

- **Membership in international or intergovernmental organizations**
  - e.g. WTO, WHO, FAO

- **Regional agreements with regulatory provisions**
  - e.g. CUSMA, CETA

- **Mutual Recognition Agreements**
  - e.g. Canada-EU MRA on Drug GMP

- **Transgovernmental networks, usually of regulators in a specific area**
  - e.g. Pharmaceutical Inspection Cooperation Scheme

- **Formal requirements to consider IRC when developing regulations**
  - e.g. Canada's Cabinet Directive on Regulation

- **Recognition of international standards through incorporation by reference**
  - e.g. ISO

- **Soft Law**
  - e.g. OECD Recommendation on GRP

- **Dialogue/informal exchange of information between regulators**
  - e.g. Canada-US-EU Galway Statement on Atlantic Ocean Cooperation

Canada’s Regulatory Cooperation Fora

Canada-United States Regulatory Cooperation Council (RCC)

Established in 2011 by U.S. President Obama and Canadian Prime Minister Harper to enhance economic competitiveness while maintaining high levels of protection for health, safety and the environment.

Canadian Free Trade Agreement (CFTA) - Regulatory Reconciliation and Cooperation Table (RCT)

Established in 2017 to reduce domestic barriers to trade, facilitate investment and labour mobility, and encourage common processes among Parties.

Canada - European Union Comprehensive Economic and Trade Agreement (CETA) - Regulatory Cooperation Forum (RCF)

Established in 2018 with the aim of identifying potential areas for cooperation, facilitating discussions between regulatory authorities, and sharing information.
Canada-United States Regulatory Cooperation Council
Canada-United States Regulatory Cooperation Council

**What?**
- Launched in February 2011
- Practical approach to regulator-to-regulator cooperation to create compatible regulations and eliminate duplication while maintaining high standards for safety, health and environment

**Who?**
- 16 Canadian and U.S. agencies with health, safety and environmental protection mandates, in partnership with stakeholders
- Central coordination and oversight by the Treasury Board of Canada Secretariat and the U.S. Office of Information and Regulatory Affairs

**Sectors?**
- Pharmaceuticals, medical devices, food, environmental standards, chemicals, cosmetics, transportation safety, dangerous goods, agriculture, energy efficiency, and aquaculture

**How?**
- Collaboration on standards, inspections, certification, testing, product approvals, and monitoring of products on the market
- 23 work plans published in 2016-2017 with work underway on 100+ initiatives
- RCC Stakeholder Forum held in Washington, D.C., December 4-5, 2018
How does the RCC work?

- Two-year work-planning cycle
- Stakeholder proposals for regulatory cooperation are accepted any time, but are especially important leading up to work plan development
- Canadian and U.S. regulators develop and publish work plans, informed by stakeholder input
- Regulators implement work plans, reporting on progress every six months
- Stakeholder Forum held every two years for interactive discussion on progress on existing work plans and stakeholder ideas for new areas

Central coordination and monitoring by RCC Secretariat, comprised of the Treasury Board of Canada Secretariat, and the U.S. Office of Information and Regulatory Affairs
Canadian Free Trade Agreement Regulatory Reconciliation and Cooperation Table
What?
• The CFTA entered into force on July 1, 2017
• The RCT is a federal-provincial-territorial body established by the CFTA to oversee the regulatory reconciliation process and promote regulatory cooperation across Canada

Who?
• Through stakeholder consultations, representatives from 13 provinces and territories, and the federal government, identify barriers for reconciliation, and task working groups to develop reconciliation agreements

Sectors?
• Occupational health and safety, transportation, standards and codes, agriculture/agri-food/aquaculture, labour mobility, drug scheduling requirements, registration requirements

How?
• Reconciliation agreement details how the trade barrier will be addressed (e.g., mutual recognition, harmonization, or some other method), which governments will participate, and the timelines for implementation.
• 29 measures identified in 2019 work plan (to be updated annually)
How does the RCT work?

• Annual work-planning cycle
• Stakeholder proposals for regulatory cooperation are accepted any time, but are especially important leading up to work plan development
• TBS and regulator review submissions to suggest to RCT
• RCT develops, revises, and publishes an annual work plan, informed by stakeholder and federal/provincial/territorial (F/P/T) input
• Working groups develop reconciliation agreements, which detail how the barrier to trade will be addressed
• RCT endorses reconciliation agreement
• Participating jurisdictions implement or take exceptions to the reconciliation agreement
Canada-European Union Comprehensive Economic and Trade Agreement Regulatory Cooperation Forum
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<th>What?</th>
<th>CETA came into force September 21, 2017</th>
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<td>CETA establishes RCF under Chapter 21</td>
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<th>Who?</th>
<th>RCF has four co-chairs: two from Canada, two from EU</th>
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<td>Central coordination and oversight by TBS, Global Affairs Canada, DG GROW and DG Trade</td>
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| Sectors? | Consumer product safety, pharmaceutical facility inspection, animal welfare (transportation of animals), cybersecurity and the Internet of Things, cosmetic-like drug products |

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<th>How?</th>
<th>Collaboration on standards, inspections, certification, testing, product approvals, and monitoring of products on the market</th>
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<td>Currently developing a rolling work plan that will begin early 2019 that will regularly add and remove issues/objectives, as necessary</td>
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How does the RCF work?

Idea Generation
- Regulator consultation
- Stakeholder submissions
- Ad hoc stakeholder requests

RCF Secretariat and Regulator Review and Analysis

Recommendation of Issues to RCF Co-chairs

RCF Co-chair Oversight
- Work Plan Item Identification
- Technical/Expert Working Groups
Successes of the RCC, RCT, and RCF

**RCC - Sunscreen Inspection Pilot**

**What:** U.S. sunscreens enter into Canada without being quarantined and tested for a second time at the border

**Benefit:** $100,000 annually of savings per sunscreen for the consumer health product industry

**RCT – Organic Labelling for Aquaculture**

**What:** New regulations broadened the types of products that could be labelled as organic

**Benefit:** Provides new market opportunities for Canadian aquaculture producers, and allows them to apply the Canada Organic Logo to their products

**RCF - Consumer Product Safety**

**What:** Timely and more detailed consumer product safety information, better informed decision making, greater access to information on recalled products

**Benefit:** Better protection from potentially dangerous consumer products, earlier removal from the market, reduced burden to regulators, collaboration on risk assessment.
International organizations can be leveraged to provide a platform for dialogue and cooperation across borders and can help address emerging global policy challenges.
Factors critical for successful regulatory cooperation:

- **System Similarities**: Foundation of good regulatory practices make the various parties comfortable working together.
- **Leadership Support**: Support from leaders, senior officials and top ranks of government.
- **Central Oversight**: Central role to facilitate and oversee initiative.
- **Trust Between Regulators**: Building confidence and trust takes time but is critical to success.
- **Stakeholder Engagement**: Strong engagement and participation from stakeholders is vital to success.
Challenges to International Regulatory Cooperation

Some of the challenges of IRC include:

- “Language” differences between trade officials and regulators
- Considering appropriateness to local needs/national interest
- Ensuring the right players are at the table
- Divergence in countries’ regulatory cultures and emphasis on health and safety
Not all international regulatory cooperation is suitable for trade agreements. Some considerations of incorporating IRC provisions in FTAs include:

- International regulatory cooperation is voluntary but FTAs tend to be enforceable through dispute settlement.
- Given limited time and resources, how likely are regulators to collaborate?
- Do the different jurisdictions involved have a central oversight body to lead IRC commitments?
- How similar are the policy frameworks to enable international regulatory cooperation?
- IRC is an alternative but not a substitute for TBT work.
- Would a GRP chapter be more appropriate?
Conclusion and Take-Aways

✔ Regulatory cooperation is both a good regulatory practice and a trade interest.

✔ It is the next frontier of reducing non-tariff barriers to trade in order to promote efficiency and decrease costs/burden.

✔ A central regulatory authority to oversee regulatory cooperation activities and bring together key players is a critical piece of the puzzle.

✔ Regulatory cooperation cannot be done in isolation; it requires support from regulators, trade officials, stakeholders, and civil society.
Thank you

For more information, visit...

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www.canada.ca/regulatory-cooperation

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Your Government at Work