



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.

1. Commit to whole-of-government policy for regulatory quality

2. Adhere to principles of open government

3. Provide oversight of regulatory policy

4. Integrate Regulatory Impact
Assessment

5. Conduct systematic programme reviews of regulatory stock

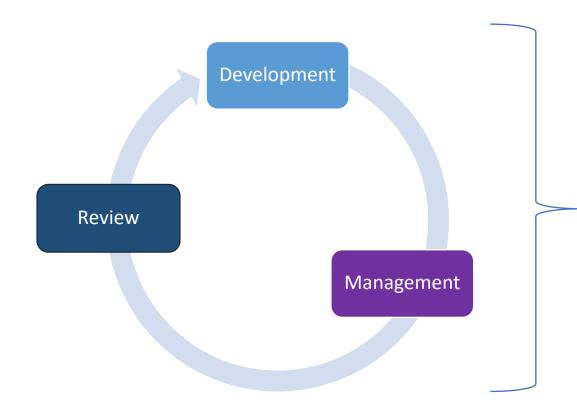
6. Regularly publish reports on performance of regulatory policy

- 7. Develop a consistent policy covering the role of regulatory agencies
- 8. Ensure effectiveness of systems for review of legality and procedural fairness
- 9. As appropriate apply risk assessment, risk management, and risk communication strategies

- 10. Promote regulatory coherence through coordination mechanisms between all levels of government
- 11. Foster the development of regulatory management capacity at subnational levels of government
- 12. Give consideration to all relevant international standards and frameworks for cooperation

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

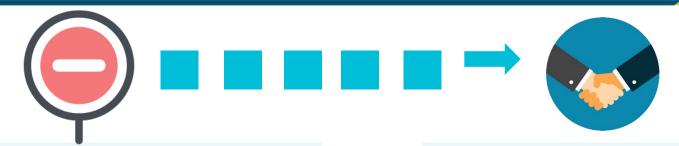


Departments and agencies are to assess opportunities for **cooperation** with other jurisdictions, domestically and internationally, on regulations and associated regulatory activities. This includes examining **alignment** of regulatory approaches and outcomes with key trading partners.

- Cabinet Directive on Regulation



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

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?

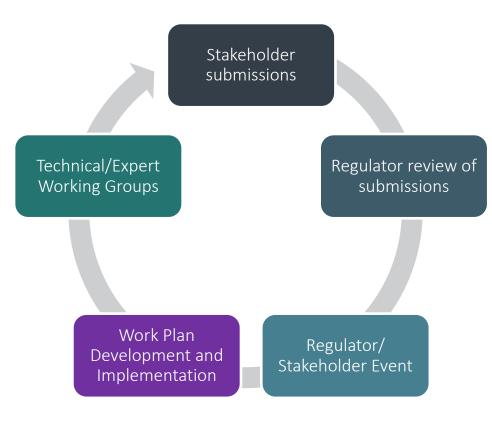
 Pharmaceuticals, medical devices, food, environmental standards, chemicals, cosmetics, transportation safety, dangerous goods, agriculture, energy efficiency, and aquaculture

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

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?

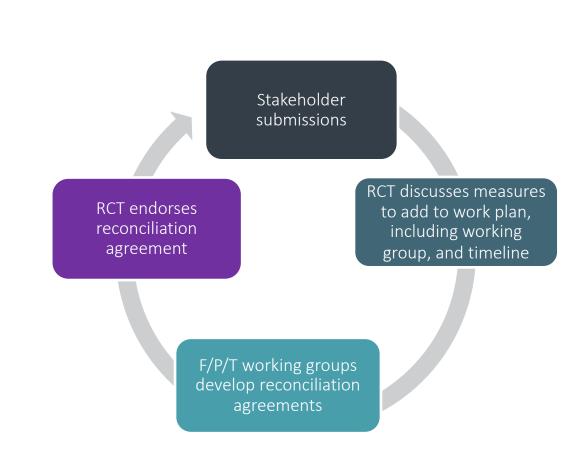
 Occupational health and safety, transportation, standards and codes, agriculture/agri-food/aquaculture, labour mobility, drug scheduling requirements, registration requirements

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

CETA Regulatory Cooperation Forum

What?

- CETA came into force September 21, 2017
- CETA establishes RCF under Chapter 21

Who?

- RCF has four co-chairs: two from Canada, two from EU
- Central coordination and oversight by TBS, Global Affairs Canada, DG GROW and DG Trade

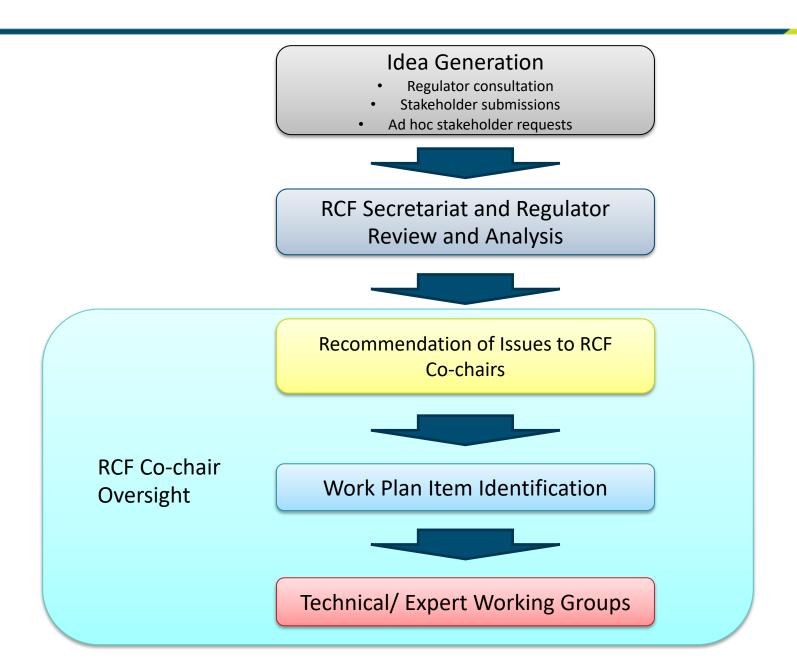
Sectors?

• Consumer product safety, pharmaceutical facility inspection, animal welfare (transportation of animals), cybersecurity and the Internet of Things, cosmetic-like drug products

How?

- Collaboration on standards, inspections, certification, testing, product approvals, and monitoring of products on the market
- Currently developing a rolling work plan that will begin early 2019 that will regularly add and remove issues/ objectives, as necessary

How does the RCF work?



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 Landscape



Organization for Economic Cooperation and Development (OECD)

- The OECD recognizes international regulatory cooperation as a Good Regulatory Practice.
- E.g. International regulatory cooperation peer reviews, Regulatory Policy Committee.



Asia Pacific Economic Cooperation (APEC)

- Many efforts are in place for APEC members to advance international regulatory cooperation.
- E.g. Workshops on IRC, joint efforts with OECD.

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EU Single Market

 The single market refers to the EU as one territory without any internal borders or other regulatory obstacles to the free movement of goods and services.



APEC

The WTO Agreement on Technical Barriers to Trade establishes obligations on its members on the preparation, adoption and application of technical regulations, conformity assessment procedures and standards



International organizations can be leveraged to provide a platform for dialogue and cooperation across borders and can help address emerging global policy challenges.

Keys to Success

Factors critical for successful regulatory cooperation:



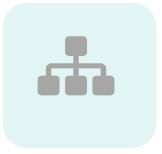
System Similarities

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:



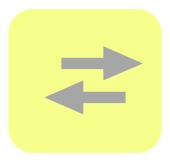
"Language" differences between trade officials and regulators



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

IRC in Free Trade Agreements (FTAs): Key considerations

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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