



**U.S.-Canada  
Regulatory Cooperation  
– Charting the Path Forward –**

**June 20, 2013  
Washington, DC**



# Outline

- RCC – Progress to Date
- Outstanding challenges
- Comparing models of regulatory cooperation
- What regulatory cooperation is and isn't
- Cooperative arrangements
- Forward path
- Stakeholder dialogue



# RCC – Progress to Date

- **RCC Action Plan contains two components:**
  - specific issue resolution; and
  - ongoing alignment
- **Progress being made in individual initiatives**
- **Most misalignment not due to fundamental differences – rather lack of synchronization and collaboration in routine regulatory system development and renewal**
- **Consideration of ongoing alignment remains at an early stage**
  - Common critical path developed to focus attention on this task in the coming months
  - Work underway to enable deeper regulatory cooperation
- **Considerable interest in additional work**
  - Timely to consider the path forward



# Outstanding Challenges

- Fundamental shift in regulatory relationship still required to secure additional benefits. For example:
  - Lower costs for industry and consumers
  - Combined regulatory expertise and effort
    - More effective and efficient collective regulatory system
  - Product availability improvement for consumers
- An issue-based “Action Plan” was a good place to start
  - Senior-level dialogue between agencies with similar mandates
  - Built common understanding of some systemic issues
  - Socialized concept of deeper cooperation and alignment
- Regulatory cooperation needs to be institutionalized – the “new normal”
- Need to engage in a dialogue on systemic alignment – regulators and stakeholders
  - Regulator discussions in working groups in the coming months
  - Opportunity for input this summer by stakeholders: industry and consumers



# Comparing Models of Regulatory Cooperation

- Several other “advanced” models of cooperation exist – don’t correlate precisely to Canada-U.S. situation, e.g.:
  - Australia-New Zealand Trans-Tasman Agreement
    - Built on successive trade agreements
    - Several joint institutions developed replacing traditional agency roles:
      - e.g. a therapeutics regulatory agency (ANZTPA)
      - e.g. a food standards organization (FSANZ)
  - European Union
    - As customs union, provides for supra-national law-making and institutions
    - Regulatory cooperation takes place through centralized rules and control
- Canada-U.S. partnership model will be about sovereign regimes but with deeper cooperation, given...
  - Similar desired outcomes, targeting high levels of protection and outcomes
  - Recognition that two effective regulatory systems already exist
  - Tradition of cooperation and strong relationships between our regulators



# Canada-U.S. ongoing regulatory alignment is not about adopting one system – it is about making strategic choices

<b>IS</b>	<b>IS NOT</b>
Alignment and cooperation in some routine areas of regulatory business only. The intention is to maintain two independent systems that are more aligned.	One regulatory system for North America.
Processes for cooperation leading up to final decisions, which will be made within our respective independent regulatory systems.	Loss of sovereignty.
In almost all circumstances, this is about alignment of work that is already underway or will be in the future. The goal is to have regulators work together, as change occurs through the normal processes, to ensure that changes in standards and systems can be aligned.	Adopt U.S. / Canadian standards.
The goal is to improve and modernize together; improve health and safety and protect the environment on both sides of the border. Improvements can be made to deliver gains in efficiency and effectiveness.	Race to the bottom.
Beyond the regulation itself, collaboration is important across several aspects of the regulatory system, such as regulatory policy, related programs and guidance, inspection and testing methods, compliance and enforcement, etc.	Simply about publishing the same regulation.
Choices will be made as to where to align and where not to – a decision by both countries. With our economies so integrated, there are many opportunities. Some opportunities may be more regional or international, and bilateral trade disputes have a specific dispute resolution process. Default is to align only when in the common interest of Canada and the U.S.	Full alignment in all areas between Canada & U.S. – ignoring interests elsewhere.



# Four Key Areas of Regulatory Business

Our analysis is that there are four key areas where regulatory cooperation could deliver significant benefits:

## **Cooperation in product reviews and approval**

- Collaborate on aligning submissions, analysis, and approval processes.

## **Cooperation in regulatory system reliance**

- Reduce and eliminate duplicative requirements by recognizing success of each others' work.

## **Cooperation in regulatory standard-setting**

- Partner on regulatory standards development, conformance (i.e., testing), and implementation / enforcement.

## **Cooperation in managing import risk at the perimeter**

- Move Canada/U.S. border activity to the external perimeter and collaborate on efforts abroad.



# An Example: Department-to-Department Cooperative Arrangements

## Overarching department-to-department regulatory cooperation arrangement

- Overarching direction and strategy
- Enabling MOU's, e.g., information and fund-sharing
- Outlines Terms of Reference and governance for the agreement
- Overall planning and synchronization

*Engagement of stakeholders for strategic sectoral input*

### Sector Plan A

*Sector plans outline priority areas for cooperation for next 3-5 years*

### Sector Plan B

### Sector Plan C

### Aligning regulatory systems – How to do it

*Each sector plan contains commitments to cooperate across the various areas of regulatory activity*

- Shared development of regulatory programs
- Shared development of tests and methodologies
- Shared compliance and enforcement activities
- Work sharing arrangements

### Annual Action Plan – What to do

*Each sector plan contains specific initiatives and deliverables, updated annually, which becomes the de facto RCC Action Plan e.g.,*

- Development of new standards in a specific area
- Joint approvals process for new products
- Common approach to 3<sup>rd</sup> country imports of a specific product

*Stakeholder input on plans and participation in implementation (e.g., pilot projects)*





## Cooperative Arrangements: Key Players and Roles

### Regulatory departments

- Develop cooperative arrangements and sector-specific multi-year and annual work plans
- Coordinate forward plans to develop; establish protocols to share funds and information; establish joint work agendas for standards and product reviews/approvals, adjust programs, testing and compliance activities
- Inform and engage stakeholders

### Stakeholders

- Assess industry needs and develop bi-national priorities
- Inform regulators of desired sectoral changes and industry impacts
- Develop bi-national sectoral expertise to assist in implementation and develop pilot projects opportunities

### Central agencies

- Develop overall strategy for cooperation (with regulators and stakeholders)
- Develop policies and guidance to enable cooperation
- Monitor and trouble-shoot implementation



# RCC Path Forward

- Work in the coming months on systemic alignment/cooperative arrangements
  - Common Canada-U.S. critical path agreed to across all working groups
- Implement deeper stakeholder-working group engagement
  - webinars – to help reach out to non-traditional groups and regional firms
- Consider regulatory cooperation moving forward
  - input from stakeholders this summer
- Government discussions before the end of the mandate on securing Canada-USA regulatory cooperation

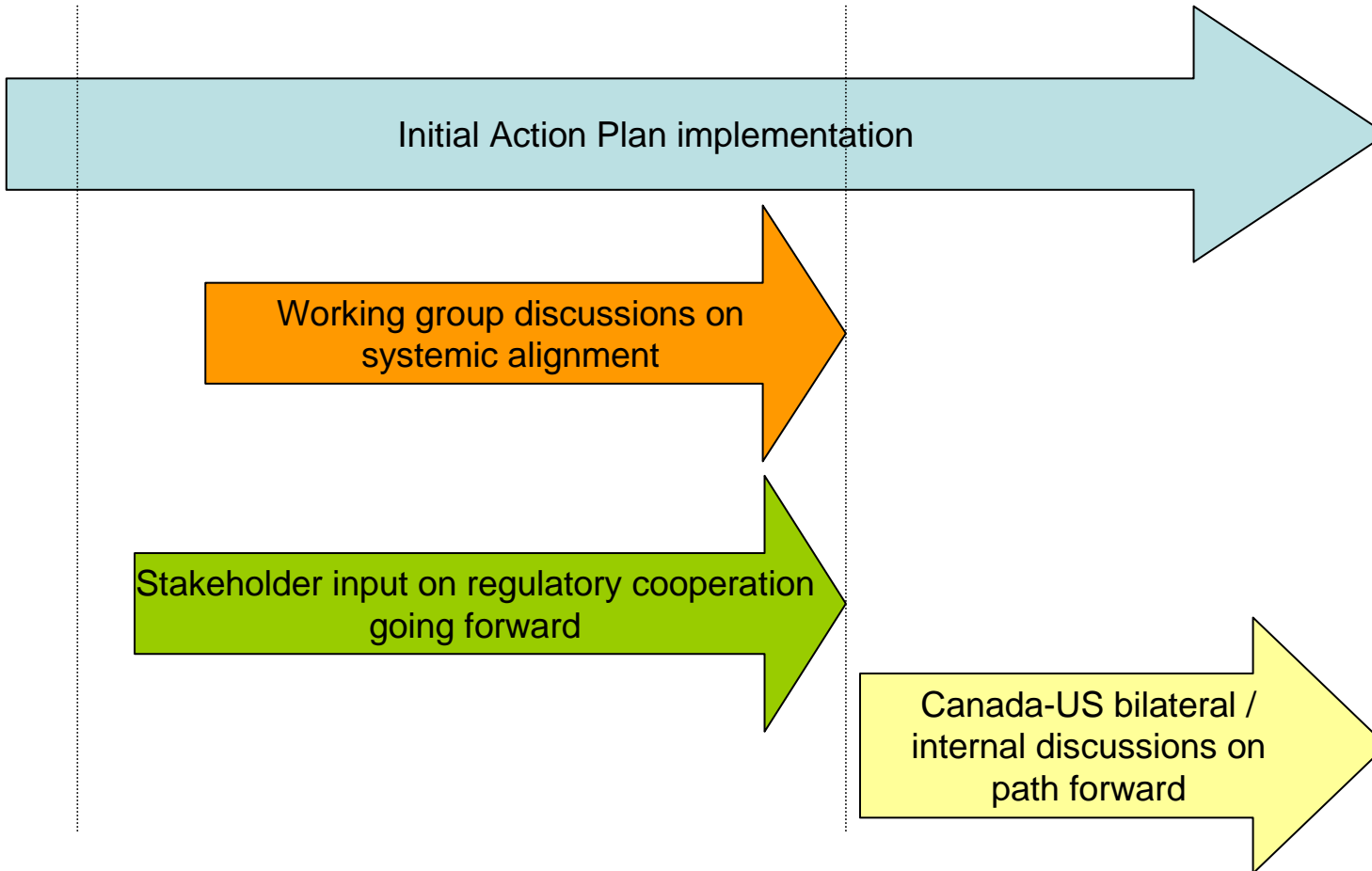


# Key Phases

June 2013

Oct 2013

March 2014





# Stakeholder Dialogue – Launching this summer

- Upcoming formal solicitation of views
  - Prompting questions in 3 areas:
    - Evolution of the action plan
    - Stakeholder role
    - Ongoing cooperation
- Formal and informal input
  - In writing to the Federal Register Notice via Regulations.gov and the Canada Gazette
  - Opportunities for discussions at your events
- Several month process
  - to allow time for thoughtful input from stakeholders and consideration
- Will be used to inform further government to government discussions this fall / winter



# **Regulatory Cooperation Council**

**[www.actionplan.gc.ca/RCC](http://www.actionplan.gc.ca/RCC)**

**[www.trade.gov/RCC](http://www.trade.gov/RCC)**