



Regulatory Cooperation Council – Update and Next Steps –

**Canadian Manufacturers & Exporters
September 16, 2013**



Overview

- Commitment to establish Canada-US Regulatory Cooperation Council announced by President Obama and PM Harper in February 2011
- Initial 29 item Action Plan developed by December 2011
- Detailed work plans initiated summer 2012
- Progress Report to Leaders in December 2012
- Stakeholder discussions in Washington, DC in June 2013
- Concurrent Canada-US stakeholder consultation on next phase of regulatory cooperation – now until October 11



Progress

- Concrete tangible results in several sectors; e.g.,
 - ✓ Common electronic gateway for drug reviews
 - ✓ Simultaneous vet drug reviews and approvals
 - ✓ Agreement on animal disease zoning
 - ✓ Joint research agenda for vehicle safety standards going forward
- Unprecedented dialogue among regulators about ongoing alignment
- Evolution of thought – focus on what institutionalized cooperation might look like
- Stakeholder engagement and sense of opportunity increased
- Central agency relationship (PCO and OMB-OIRA) strong and like-minded



Lessons Learned and Considerations Moving Forward

- Fundamental shift in regulatory relationship still required to secure additional benefits, such as:
 - Lower costs for industry and consumers
 - More effective and efficient collective regulatory system
 - Combined regulatory expertise and effort
 - 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
- Fiscal restraint is a tactical challenge, strategic opportunity
 - The RCC is as an opportunity for greater partnership leading to collective regulatory effectiveness and efficiency
- Regulatory cooperation needs to be institutionalized – the “new normal”



Cooperative Arrangements: A Potential Model Presented on June 19/20

Characteristics

- Formal arrangements between Canadian and US departments
 - Sets out governance, med/long term strategies and priorities
 - Provides for sector-based multi-year direction
 - Annual RCC work plans
- Enhanced, structured role for stakeholders
- Target four key areas of routine regulatory business
 - Product reviews and approvals
 - Regulatory system reliance
 - Standard setting
 - Managing import risks at the perimeter

Assumptions

- Placing regulators in the lead is the best way to create and sustain change
- Collaboration is required across several aspects of reg system, such as reg policy, related programs and guidance, inspection and testing, compliance and enforcement
- Maintain two independent systems – decisions remain sovereign but work leading to them is better synchronized and collaborative



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 3rd country imports of a specific product

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



RCC Today

- Now entering last six months of initial Action Plan
- Examination underway of changes required to facilitate ongoing cooperation
 - policy and legal changes: information sharing, fund sharing, aligned/joint regulatory processes
 - Institutionalized process between regulators (“cooperative arrangements”)
- Better positioned to consider more “game changing” efforts and additional initiatives
- Opportunity for reflection on path forward before spring 2014
- Comments now being solicited from stakeholders via Canada Gazette and US Federal Register on next phase of regulatory cooperation



Key Areas for Stakeholder Input

Issues / Sectors

- New issues within sectors covered by existing Action Plan (e.g., health, agriculture, transportation)
- New sectors (e.g., energy) for RCC consideration
- New forms and models for standards cooperation – e.g., consideration of privately developed / federally referenced standards
- Emerging technologies and emerging regulatory challenges

Institutionalized cooperation

- Recommendations on possible approaches – e.g., agency-to-agency cooperative arrangements
- Enhance existing approaches and/or create new arrangements where non-existent
- Views on the “potential model” – will it get the job done?

Stakeholder role

- How should stakeholders engage with Canadian and US regulators on priority issue identification?
- Ideas on new governance arrangements
 - between Canadian and US industry
 - between government and industry
- How can industry help facilitate implementation?



Attention Required By Key Actors in Short-term

Departments / Agencies

- Simultaneous dialogue on cooperative arrangements between regulators already involved in the Action Plan

Central Agencies

- Discussion on overall direction, including how to approach new phase of work
- Nature of institutionalized changes – both short- and long-term
- Consideration of how Canada-US regulatory cooperation fits in broader context (NAFTA, other regional trade agreements)

Stakeholders

- If regulatory cooperation is important to your company or industry, now is the time for your engagement with government concerning issues / governance / stakeholder role
 - Binational submissions, if possible, would be helpful

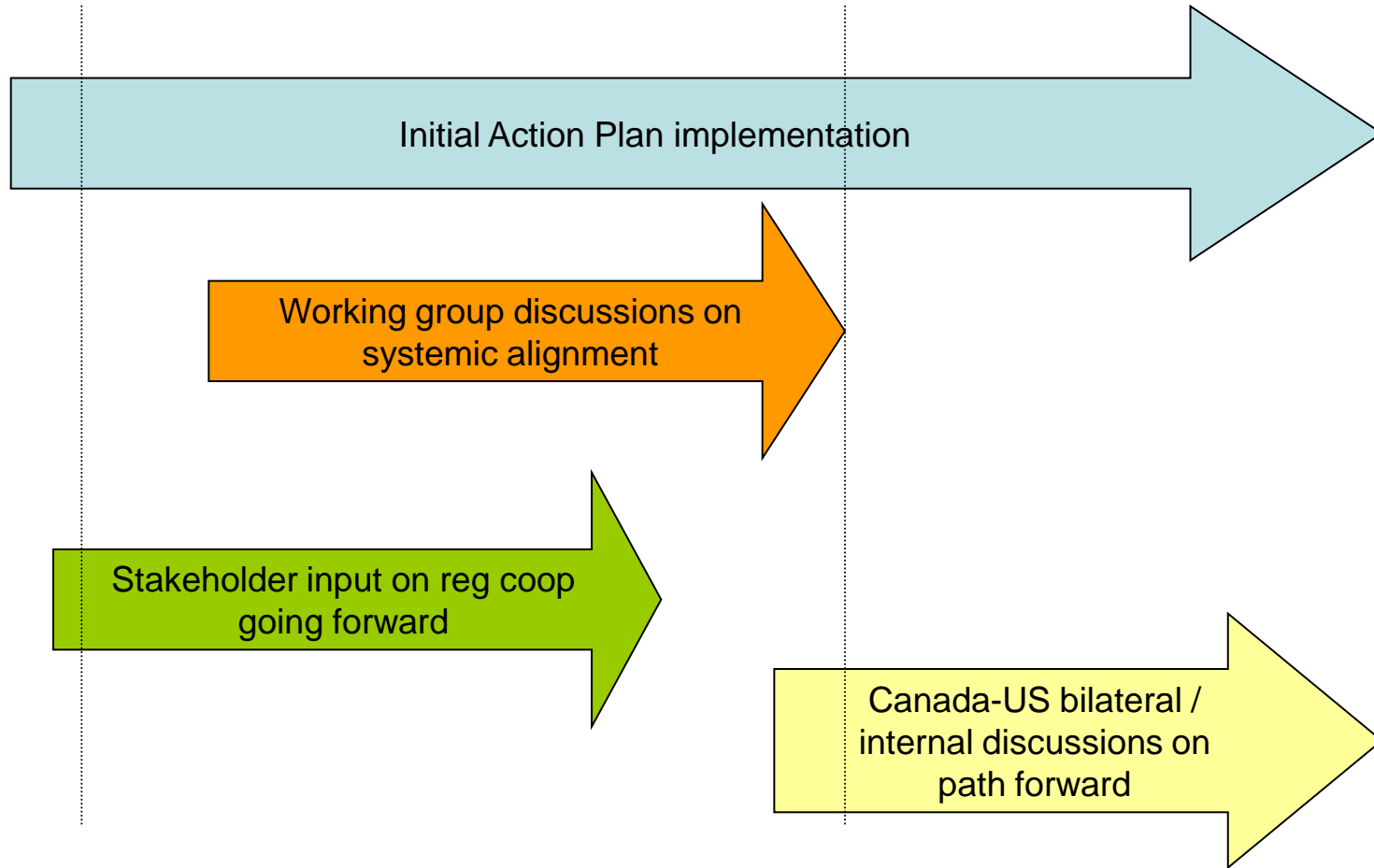


Activities for Next Phase

September 2013

December 2013

March 2014





Regulatory Cooperation Council

www.actionplan.gc.ca/RCC

www.trade.gov/RCC