



**Regulatory Cooperation Council
Nanotechnology Initiative
Final Results Workshop**

January 14, 2014



**Session 1:
Overview of the Canada-US Regulatory
Cooperation Council (RCC) and the RCC
Nanotechnology Initiative**

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What is the Regulatory Cooperation Council?

- On February 4, 2011, Prime Minister Stephen Harper and President Barack Obama announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) to increase regulatory transparency and coordination between the two countries
- Since 2012, the RCC has been working in 29 areas, including nanotechnology, to better align the regulatory environment between Canada and the United States through a variety of tools, such as:
 - enhanced technical collaboration
 - mutual recognition of standards
 - joint work sharing
- The RCC Joint Action Plan is aimed at:
 - better aligning the regulatory environment between Canada and the United States
 - increasing regulatory transparency and coordination between the two countries
 - developing systemic solutions; and
 - providing a strong foundation for ongoing cooperation



Regulatory Cooperation Council Milestones

- February 4, 2011: Creation of RCC announced by President Barack Obama and Prime Minister Stephen Harper
- December 7, 2011: Release of RCC Joint Action Plan by President Obama and Prime Minister Harper
- January 30-31, 2012: Stakeholder consultations in Washington, DC on to seek input into work plans
- May 17, 2012: Public posting of the completed 18-month work plans (Nanotechnology Work Plan)
- December 2012: Publication of 2012 Progress Report to Leaders
- June 2013: Stakeholder workshop in Washington DC to present on progress to date and discuss next steps
- September 2013: Publication of consultation document on RCC next steps in Canada Gazette and the US Federal Registry for a 60 day public comment



RCC Nanotechnology Initiative: Overview

Overall Outcome of Nanotechnology Work Plan:

- Share information and develop joint approaches on regulatory aspects of nanomaterials - including terminology and nomenclature, as well as risk assessment and management

Primary focus of Work Plan:

- Nanomaterials considered to be new substances regulated in Canada and the US under the Canadian Environmental Protection Act (CEPA) and Toxic Substances Control Act (TSCA)

Contributing Departments and Agencies:

- US Office of Management and Budget (OMB), Office of Information and Regulatory Affairs: Jim Kim and Danielle Jones
- US Environmental Protection Agency (EPA): Jeff Morris, Deputy Director for Programs, Office of Pollution Prevention and Toxics
- Canadian Privy Council Office (PCO): Robert Carberry, RCC Secretariat
- Environment Canada (EC): Karen Dodds, Assistant Deputy Minister, Science and Technology Branch
- Health Canada (HC): Hilary Geller, Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch



RCC Nanotechnology Initiative

1. Principles: Identification of common principles for the regulation of nanomaterials to help ensure consistency for industry and consumers in both countries
2. Priority-Setting: Identification of common criteria for determining characteristics of industrial nanomaterials of concern/no-concern
3. Risk Assessment/Management: Sharing of best practices for assessing and managing the risks of industrial nanomaterials
4. Commercial Information: Characterization of existing commercial activities and identification of gaps and priorities for future knowledge gathering for industrial nanomaterials
5. Regulatory Cooperation in Areas of Emerging Technologies: Development of a model framework providing key elements and approaches to regulating products and applications of emerging technologies with respect to potential impacts on the environment, human health, food or agriculture



Policy Principles for the Regulatory Oversight of Nanomaterials

Objective: Identification of common principles for the regulatory oversight of nanomaterials to help ensure consistency for industry and consumers in both countries



US Policy Principles for Nanomaterials

- In June 2011, the U.S. published '*Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials*'
- The Memorandum was signed by the heads of the following executive offices of the President of the United States:
 - Office of Management and Budget
 - United States Trade Representative
 - Office of Science and Technology Policy
- These offices, along with the National Economic Council, led a multi-agency consensus-based process to develop the principles
- These principles are meant to guide the development and implementation of policies for the oversight of nanotechnology applications and nanomaterials, without superseding existing statutes and regulations



Accomplishments under the RCC Nanotechnology Initiative

- Canada reviewed and analyzed the U.S. Policy Principles to determine congruency with the Canadian government's existing approaches
- Environment Canada, in cooperation with other federal departments and agencies, determined that the US Policy Principles were entirely applicable within a Canadian context
- The US Policy Principles were placed in a Canadian and a RCC context, and a document '*RCC Nanotechnology Policy Principles for Decision-Making Concerning Regulation and Oversight of Nanotechnology and Nanomaterials*' was developed and supported by senior management from all participating regulatory departments and agencies
- This document was posted for a 60-day public comment period ending July 17, 2013; stakeholder feedback was supportive



Summary of Policy Principles for the Regulatory Oversight of Nanomaterials in Canada and the US

- To ensure scientific integrity, *base decisions on the best available scientific evidence*
- Seek and develop *adequate information with respect to the potential effects of nanomaterials on human health and the environment* and take into account new knowledge when it becomes available
- To the extent practicable, *provide sufficient flexibility in oversight and regulation* to accommodate new evidence and learning on nanomaterials



Summary of Policy Principles for the Regulatory Oversight of Nanomaterials in Canada and the US

- Base decisions on an *awareness of the potential benefits and the potential costs of such regulation and oversight*, including recognition of the role of limited information and risk in decision making
- Consistent with current statutes and regulations, *strive to reach an appropriate level of consistency in risk assessment and risk management*, using standard oversight approaches to assess risks and benefits and manage risks, considering safety, health and environmental impacts, and exposure mitigation
- Mandate *risk management actions appropriate to, and commensurate with, the degree of risk* identified in an assessment



Summary of Policy Principles for the Regulatory Oversight of Nanomaterials in Canada and the US

- To the extent feasible and subject to valid constraints (e.g. confidential business information), develop relevant information in an *open and transparent manner*, with opportunities for stakeholder involvement and public participation
- *Communicate information to the public* regarding the potential benefits and risks associated with specific uses of nanomaterials
- Seek to *coordinate internally and with stakeholders* to address the breadth of issues, including potential health and safety, economic, environmental, and ethical issues associated with nanomaterials
- Encourage *coordinated and collaborative research across the international community* and clearly communicate the regulatory approaches and understanding of Canada and the US to other nations



Moving Forward

- Through the RCC Nanotechnology Work Plan, Canada has developed a set of policy principles entirely consistent with those developed by the US

The two countries now share common principles for the regulatory oversight of nanomaterials



Annex



US-Canada Cooperation on Chemicals Assessment and Nanomaterials

- Participate in ongoing **international work** to optimize efforts:
 - Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials
 - Informs on human health and environmental safety implications
 - ISO Technical Committee 229 “Nanotechnologies”
 - Develops standards for nanotechnologies
 - ILSI NanoRelease project
 - Research collaboration to quantify release of nanomaterials from consumer products
- Engage in **bilateral initiatives** to share information:
 - *Ad-hoc* engagement on substance-specific risk assessments and management
 - Consultation on Substances Management (CoSM)
 - Formed in 2003 to increase cooperation on chemicals management
 - Four Corners Agreement
 - Facilitated information exchange on new substances