

# **Canada-US Regulatory Cooperation Council Nanotechnology Initiative**

## **Introduction & Background**

**Stakeholder Webinar  
November 28, 2012**

**Presenters:**

David Morin, Director General, Science and Risk Assessment, Environment  
Canada

Karen Lloyd, Director General, Healthy Environments and Consumer Safety  
Branch, Health Canada

Jeff Morris, Deputy Director for Programs, Office of Pollution Prevention and  
Toxics, United States Environmental Protection Agency

# Webinar Overview

1. Background on overall RCC initiative
  - Nanomaterials in the regulatory context
  - US-Canada cooperation on chemicals and nanomaterials
  - Introduction of RCC Nanotechnology Work Plan
  
2. RCC Nanotechnology Work Plan Elements
  - Objectives, progress to date and intended outcomes
  
3. Next Steps
  - Stakeholder engagement
  - Upcoming events

# 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
- The RCC is working in 29 areas, including nanotechnology, to better align the regulatory environment between Canada and the United States through a variety of tools:
  - enhanced technical collaboration
  - mutual recognition of standards
  - joint work sharing
- This is an effort to improve regulatory alignment and develop systemic solutions
- RCC Joint Action Plan provides a strong foundation for ongoing cooperation

# Key Mechanisms for Regulatory Cooperation

- Reliance on each others' regulatory systems
  - Reduce and eliminate duplicative requirements by recognizing success of each others' work
- Regulatory Standard Setting
  - Partner on regulatory standards development, conformance (e.g. testing), and implementation / enforcement tools
- Product Approval
  - Collaboration on aligning submissions, analysis, and approval processes
- Perimeter Challenges
  - Joint focus of efforts on challenges and threats from offshore and avoid requirements at the U.S.-Canada border
- Compliance and Enforcement
  - Supporting each other efforts in ensuring regulatory compliance and enforcement

# Regulatory Cooperation Council – Progress to Date

- Release of RCC Joint Action Plan on December 7, 2011 by President Obama and Prime Minister Harper
- Bilateral working groups led by senior officials from regulatory agencies were tasked with developing work plans with specific objectives, deliverables and milestones for tangible progress within the RCC's two-year mandate
- Stakeholder consultations took place in Washington, DC on January 30-31, 2012 to seek input into work plans
- Public posting of the completed work plans in May 2012
  - Nanotechnology work plan posted by US and Canada (see Annex for links)

# Regulatory Context for Nanomaterials

- No single regulatory definition for nanomaterials in Canada or the US
  - Generally recognized as materials having 1 or more dimensions in the nanoscale (typically 1-100nm); or with dimensions above or below 1-100nm exhibiting nanoscale phenomena
  - May exhibit novel properties due to their nanoscale size as compared to their non-nanoscale counterparts
- Used in a broad range of applications and sectors
- Existing regulatory frameworks for chemicals applicable
- No nanomaterial specific regulations in Canada and the US

# 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

# US Legislative Framework for Nanomaterials

- Pesticides – Federal Insecticide, Fungicide, and Rodenticide Act
- Foods, Food Additive, Drugs, Cosmetics or Medical Devices – Federal Food Drug and Cosmetic Act
- Consumer Products – Consumer Product Safety Act
- Workers – Occupation Safety and Health Act
- **Industrial Chemicals - Toxic Substances Control Act**

# US Regulatory Framework for Nanomaterials

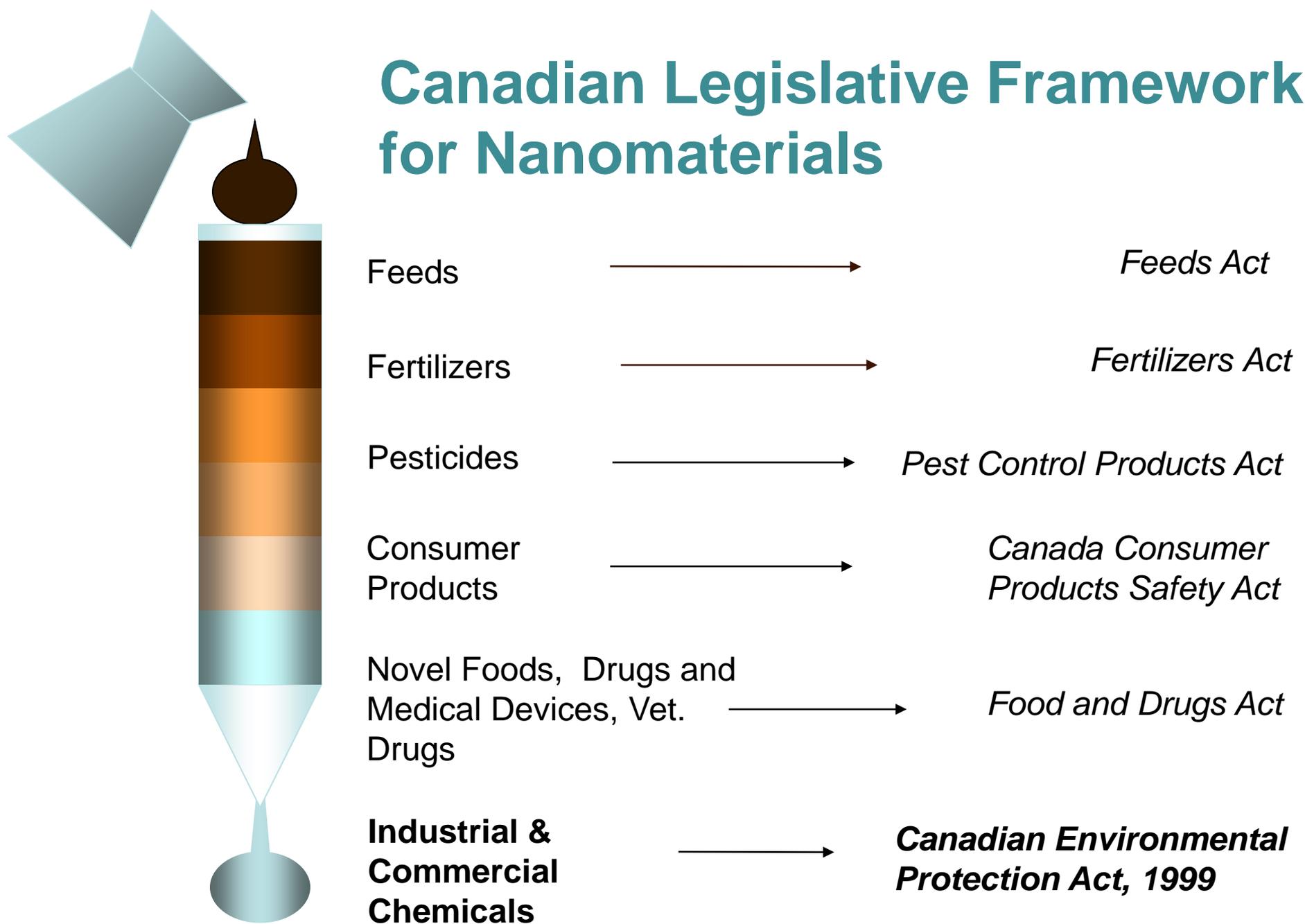
## Premanufacture Notification Regulations

- Reporting Requirements
  - Any substance that is not on the TSCA Inventory is classified as a new chemical
  - Prior to manufacture or import of a new chemical for general commercial use, a notice must be filed
- Review Period
  - Premanufacture Notice subject to a 90-day review period
  - Low Volume and Low Release Exposure Exemptions are subject to a 30-day review period
  - To address potential unreasonable risks EPA may prohibit manufacture, require testing, or issue consent orders and significant new use rules (SNURs) with requirements to mitigate potential risks and exposures

# US Policy Principles for Nanomaterials

- Communicated through a June 9 2011 memorandum to US executive departments
- “Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful”
- Principles emphasize transparency, appropriate consistency across federal agencies, collaboration, consideration of both benefits and risks, and adaptability to new information and advances in scientific understanding

# Canadian Legislative Framework for Nanomaterials



# Canadian Regulatory Framework for Nanomaterials

## **New Substances Notification Regulations (Chemicals and Polymers)**

- Any substance, including a nanomaterial, that is not on the Domestic Substances List (DSL) is classified as a new substance
- Prior to manufacture or import of a new substance above trigger quantities, a notification must be submitted
- Trigger quantities
  - Import/manufacture volume thresholds
  - Annual triggers (by calendar year)
  - Range from 100 kg/yr to 10,000 kg/yr
  - Increasing information requirements as volumes increase
- Assessment period
  - Assessment period ranges from 5 to 75 days
  - If there are concerns with the notified substance risk management options may include prohibitions, ministerial requests, ministerial conditions and Significant New Activity Notices (SNAcs)

# RCC Nanotechnology Initiative

## 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*

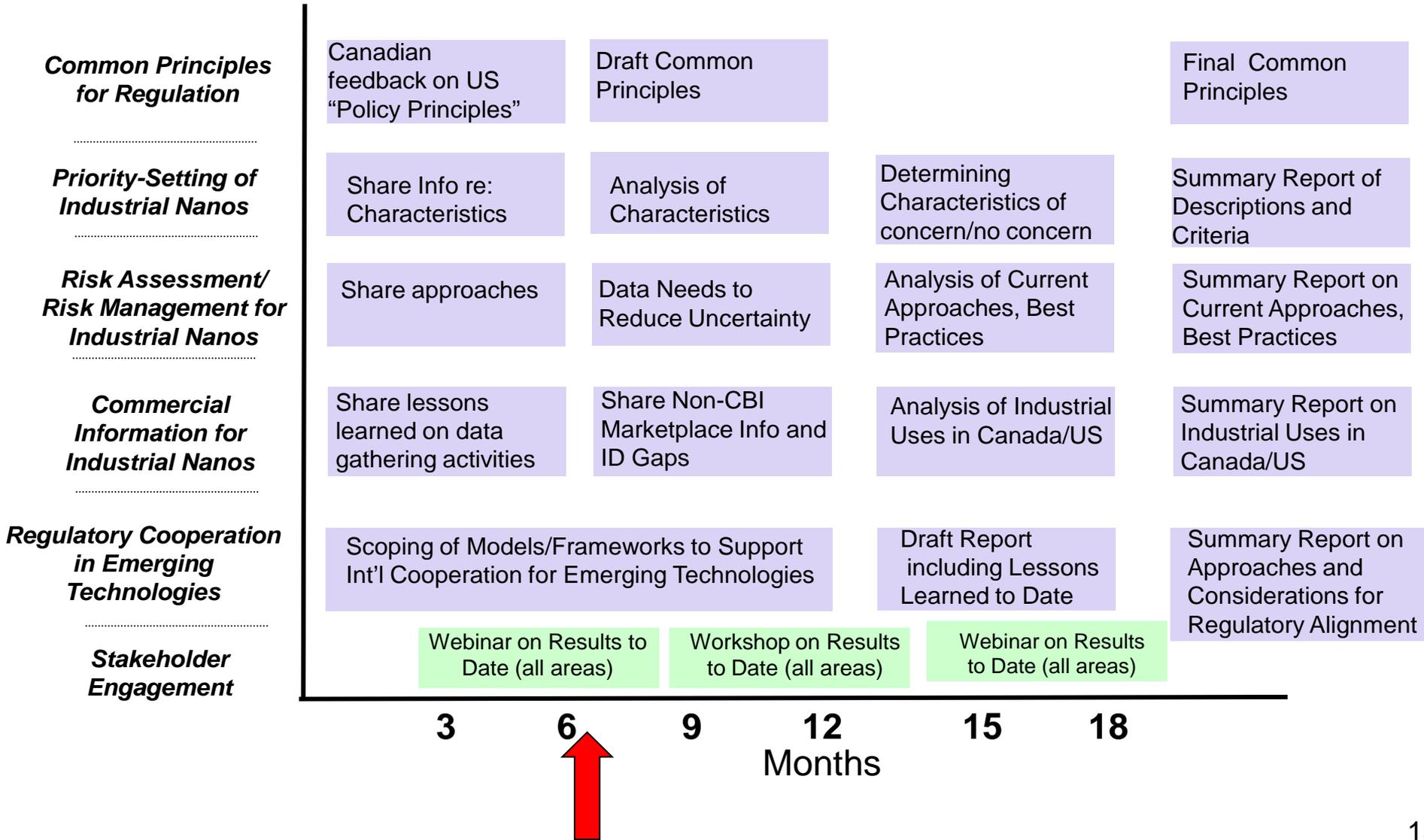
## Lead Agencies:

- US Office of Management and Budget (OMB), Office of Information and Regulatory Affairs: Margaret Malanoski
- 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 Work Plan: 5 Work Elements

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

# Proposed Timelines for RCC- Nanotechnology Work Plan



# Annex: Nanotechnology Work Plan

- Published on Canadian website at:
  - <http://www.eap.gc.ca/eng/feature.asp?pagelId=404> (English)
  - <http://www.eap.gc.ca/fra/feature.asp?pagelId=404> (French)
- Published on US website at:
  - <http://www.trade.gov/RCC>

# **Canada-US Regulatory Cooperation Council Nanotechnology Initiative**

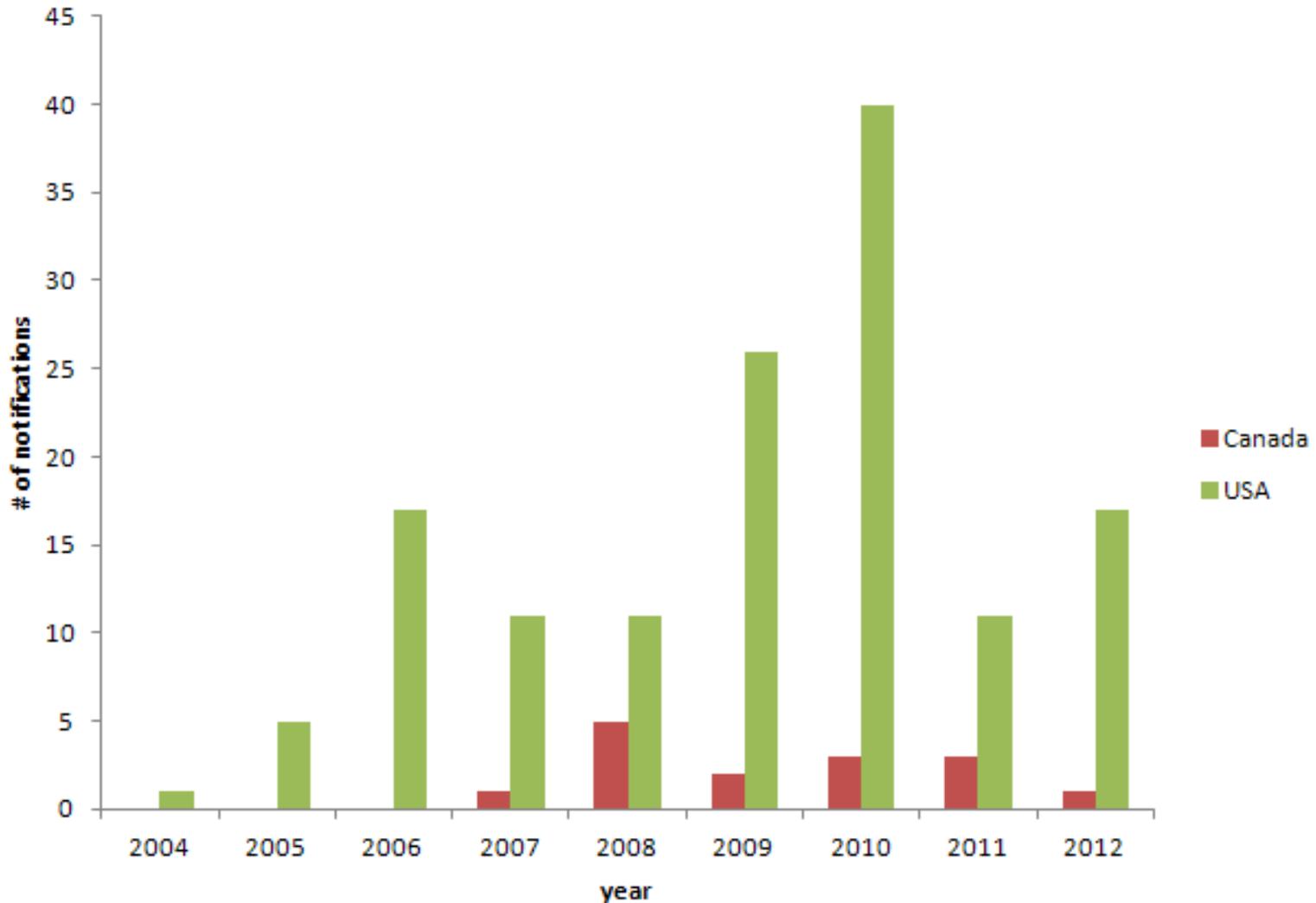
## **Work Plan Elements**

# Overview

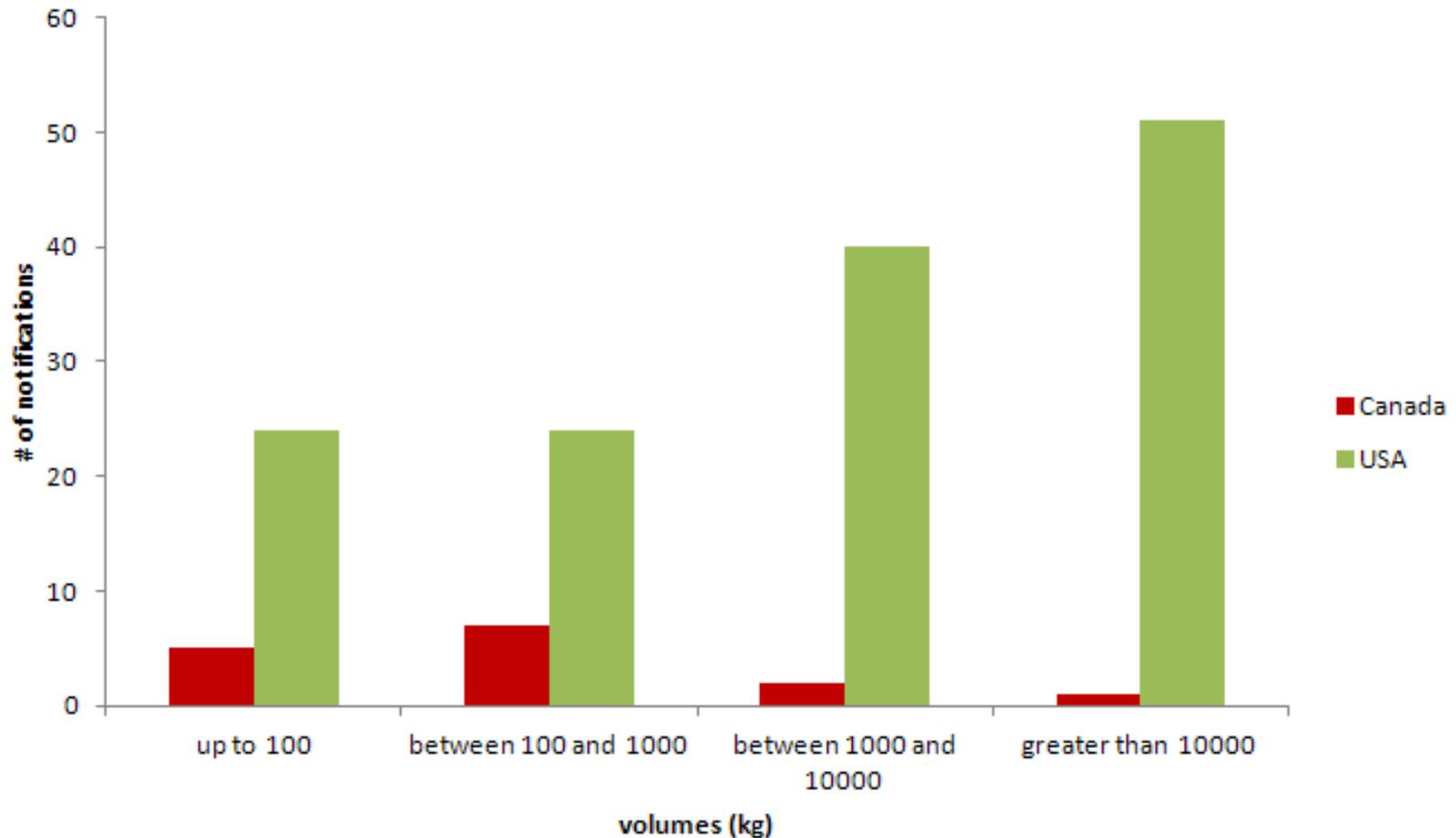
- Preliminary findings and observations from the New Substances Programs in Canada and the US
- Confidential Business Information (CBI) challenges
- Information on RCC Nanotechnology Work Plan Elements
  - Objectives
  - Deliverables
  - Progress

# Preliminary Findings and Observations

# Number of nano-related assessments per year under New Substances TSCA/CEPA

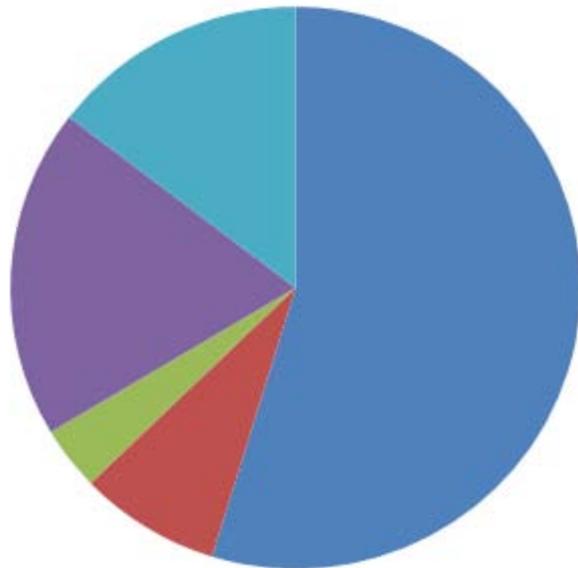


# Production volumes of nanomaterial notifications under CEPA/TSCA



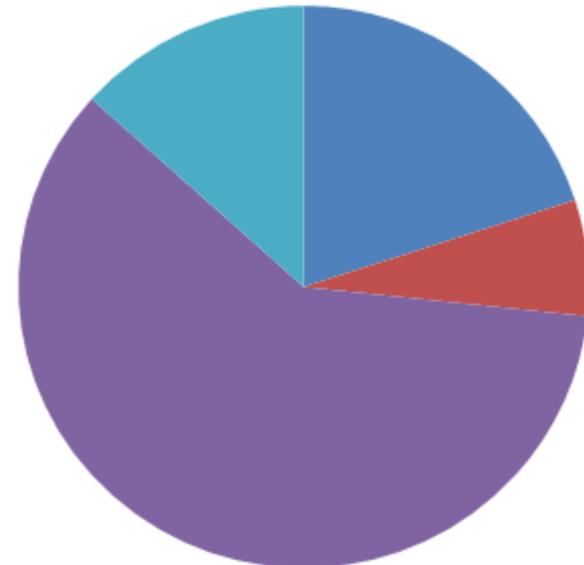
# Types of nanomaterials received through the New Substances TSCA/CEPA Programs

## USA



Total # of notifications: 137

## Canada



Total # of notifications: 16

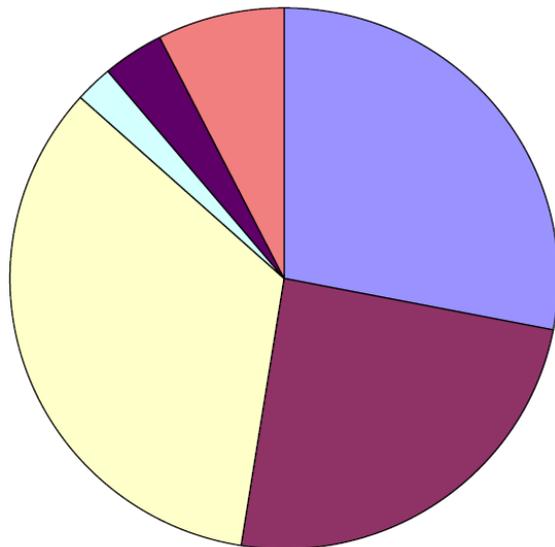
- Inorganic Carbon
- Heterogenous Substance
- Metals
- Mixed Metal Oxides
- Organic carbon

# Notified Uses of Nanomaterials under CEPA/TSCA

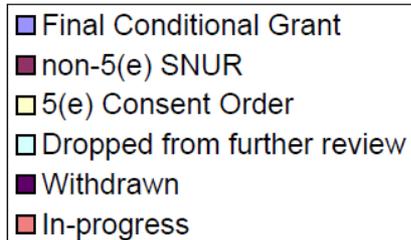
- US
  - 137 notifications
  - Most prevalent: coatings, chemical intermediate,, conductive additives, dyes/inks, mechanical strength additives
    - Others: Abrasive, batteries, catalyst, chemical resistance additive, cleaning, filler additive, filtration, lighting, lubricant/dispersant, optical coatings photovoltaics, sensor
- Canada
  - 16 notifications
  - Most prevalent: coatings
    - Others: inks, effluent treatment, composites, paints, textiles

# Regulatory decisions under TSCA/CEPA

## USA



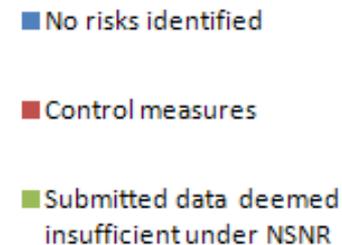
Total # of notifications: 137



## Canada



Total # of notifications: 16



# Confidential Business Information (CBI)

- In order to enhance technical and regulatory collaboration between Canada and the US, regulators need to maximize data sharing between the two programs
  - Currently, there remain significant challenges in sharing information between Canada and the US due to large number of confidentiality claims
- In both Canada and the United States, CBI can be shared only with the written permission of the data owner (US uses specific limited disclosure agreement forms)
  - Obtaining approval of each company not feasible
- Aggregating data can mask trends
- Would like to be able to share information between US EPA and Canada to better inform our regulatory programs and risk assessment/management approaches
  - **General Substance Information:** substance name, company, applications, volumes.
  - **Technical substance specific information:** physchem properties, technical studies, use pattern information, etc...
- What would we like from Industry?
  - More information on the commercial distribution of nanomaterials
  - More transparency, claiming confidentiality of only that information absolutely critical to market advantage
- Industry engagement will allow Canada and the US to make better informed decisions, and where possible, align approaches between the two countries

# **Information on RCC Nanotechnology Work Plan Elements**

# RCC Nano Work Element 2: Priority Setting

- **Co-Chairs**

- Yasir Sultan (Environment Canada)
- Tracy Williamson (US Environment Protection Agency)

# Work Element 2 (Priority Setting)

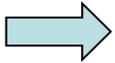
## Objective

- Identification of common criteria for determining characteristics of industrial nanomaterials
  - Examine how the two jurisdictions identify nanomaterials under current regulatory regimes; and
  - Identify common criteria to provide greater regulatory certainty for governments and industry across jurisdictions (Can/US)

# Priority Setting: Activities

- **August – November 2012:**

- Share available scientific evidence regarding characteristics of industrial nanomaterials including that obtained from existing international fora (eg. OECD Working Party on Manufactured Nanomaterials).



- **November – May 2013:**

- Initiate an analysis of characteristics of select nanomaterials: regulatory review similarities, differences, reasons for them.
- Initiate discussions on approaches to consider for common definitions and terminology.

- **May – November 2013:**

- Develop draft criteria for determining characteristics of industrial nanomaterials of concern/no-concern.

- **Beyond November 2013:**

- Draft technical language providing common descriptions and criteria of classes of industrial nanomaterials, and incorporate into summary report
- Draft document on common CAN/US approach to definition, characteristics and test methods for assessing industrial nanomaterials.

# Progress to date

- Requesting information from different regulatory programs in Canada and the US to determine:
  - How nanosubstances are identified for review (e.g. reporting triggers)
  - Classification of nanosubstances for review (e.g., chemical composition, physical attributes)
  - Type of nano-specific information requested:
    - What types of physico-chemical property data do the programs request?
    - Are there differences in desired data based on the category of nanosubstance (e.g. nanotube vs nanometal oxide)?
    - What other information is requested regarding the nanosubstance (e.g., functionality, manufacturing process, doping)?
  - Risk management actions taken based on the category of nanosubstance (e.g. nanotube vs nanometal oxide)

# Progress to date

Information requested	US	Canada
<i>Identification of nanomaterials for review</i>	<ul style="list-style-type: none"> <li>• At least 10% of the primary particles are 1 to 100 nm in two dimensions</li> <li>• Particles also exhibit properties unique to their nano size</li> </ul>	<ul style="list-style-type: none"> <li>• 1 to 100 nm in any one or more dimension</li> <li>• Particle size information is requested.</li> <li>• In the cases where the bulk form is notified, literature is scanned to see if the nanoform of that substance exists</li> </ul>
<i>Categorization of nanomaterials for review</i>	<ul style="list-style-type: none"> <li>• EPA has reviewed &gt; 250 PMNs and NMSP submissions for nanosubstances</li> <li>• Most fit into the New Chemicals category for poorly soluble, respirable particulates</li> <li>• Additional commonalities have been identified for different categories based primarily on chemical identity</li> </ul>	<ul style="list-style-type: none"> <li>• EC/HC have reviewed 16 NSNs on nanosubstances and 33 NSNs classified as potentially being manufactured on the nanoscale</li> <li>• Assessments are done on a case-by-case basis</li> </ul>

# Progress to date

Information requested	US	Canada
<i>Type of physico-chemical property data requested by type of nanomaterial</i>	<ul style="list-style-type: none"> <li>•Case by case</li> <li>•For carbon nanotubes: surface charge, surface chemistry, water solubility, density, and aggregation/agglomeration,</li> <li>•For metal oxides: surface area, surface charge, surface chemistry, porosity, water solubility, density, and aggregation/agglomeration</li> </ul>	<ul style="list-style-type: none"> <li>•No difference in requested data based on the category of the nanosubstance other than shape specific characterization (e.g., walls for tubes)</li> <li>•Information requested generally includes: particle specific characterization, water solubility, particle size as administered in toxicity test, agglomeration/aggregation, shape, surface area and surface charge</li> </ul>
<i>Other information requested</i>	<ul style="list-style-type: none"> <li>•Case by case</li> <li>•All information typically submitted in a PMN for a domestically manufactured substance is required</li> </ul>	<ul style="list-style-type: none"> <li>•Case by case</li> <li>•All information typically submitted in a NSN for a domestically manufactured substance is required.</li> <li>•Leachability test is requested if the substance is used in situations where leaching may be a possible route of exposure (e.g., coatings),</li> </ul>
<i>Risk management decisions for nanomaterials</i>	<ul style="list-style-type: none"> <li>•The final risk call is typically made on a case by case basis</li> </ul>	<ul style="list-style-type: none"> <li>• The final risk call is typically made on a case by case basis</li> </ul>

# Progress to date

- Preliminary observations on categorizing nanomaterials for the purposes of risk assessment and management:
  - Primarily case-by-case
  - Challenges with identifying nanomaterials (e.g., methods to determine pchem characteristics)
  - Carbon nanotubes (CNTs): High level of concern – exposure dependant
  - Metal oxides: assumed to have low solubility in water
  - Metals: availability of ionic metal considered
  - Organics (e.g., dyes, polymers): May not exhibit properties unique to nano

# Work Element 3: Risk Assessment / Risk Management

- **Co-chairs**
  - Myriam Hill (Health Canada)
  - Todd Stedeford (US Environmental Protection Agency)

# Work Element 3 (Risk Assessment / Risk Management) Objective

- Share best practices for assessing and managing the risks of industrial nanomaterials by:
  - Sharing information on regulatory triggers, regulatory requirements, timelines and risk management options available to each jurisdiction
  - Sharing information on methodologies, models and tools used by each jurisdiction
  - Sharing information on risk assessment / risk management approaches and outcomes for each jurisdiction

# Risk Assessment / Risk Management : Activities

- **August – November 2012:**
  - Share current experiences and approaches associated with Risk Assessment (RA) & Risk Management (RM) of industrial nanomaterials in Canada and the United States, including those obtained from existing international fora (e.g., OECD Working Party on Manufactured Nanomaterials)
- **November – May 2013:**
  - Identify data gaps which contribute to uncertainties for conducting RA and RM on industrial nanomaterials
  - Initiate pilot project on comparing RAs through case studies of nano substances, including those put forth by industry
- **May – November 2013:**
  - Initiate a review of current RA and RM approaches for industrial nanomaterials in Canada and the United States identifying, where possible, best practices
  - Finalize pilot project RAs of selected industrial nanomaterials
- **Beyond November 2013:**
  - Complete review of current RA and RM approaches and best practices for RA and RM of industrial nanomaterials, and incorporate into summary report
  - Identify opportunities for and barriers to ongoing collaborations and regulatory alignment

# Progress to date

- Information shared on:
  - Regulatory triggers
  - Assessment timeframes
  - Information requirements
  - Risk assessment methodologies: tools, models, and approaches
  - Risk management approaches
- Preliminary findings:
  - Differences in reporting thresholds between Canada (volume-tiered thresholds) and the US (must notify prior to commencement at any volume, however may be eligible for exemptions)
  - Differences in assessment timeframes and information requirements
  - Many similarities in risk assessment approaches and some differences in selecting conservative scenarios (e.g. environmental release)
  - US considers occupational exposure while in Canada this falls under provincial mandate
- A contract is being initiated to look at the similarities and differences between the two regulatory programs in more detail

# Risk Assessment - Risk Management: Case Study

**The purpose of the “Case Study” is to compare risk assessment/risk management practices in Canada and the US in order to highlight and identify best practices, data gaps and differences between the two jurisdictions. This process is not meant to be an assessment prioritization process**

- Nominations included the following information:
  - Chemical name and commercial applications of nanomaterial
  - Whether the nanomaterial had been notified to/reviewed by either jurisdiction
  - Information on exposure and environmental fate of the nanomaterial and a complete list of available test data (including analogues)
  - Acknowledgement that for the purposes of the pilot project, both parties (Canada and the US) would be able to freely exchange information, including confidential business information (CBI)
- Four nanomaterials were nominated:
  - Multiwall Carbon Nanotubes (MWCNTs), NanoCrystalline Cellulose (NCC), Nano Silver (nAg), Titanium Dioxide (nTiO<sub>2</sub>)

# Nanomaterial Case Study Selection

Nanomaterial	MWCNT	NCC	nAg	nTiO2
Applications	Resins, coatings, and composites	Paints, coatings, composites, in oil drilling	textiles	-No information provided
Regulatory status in Canada and the US	Notified in both countries	Notified only in Canada	Not notified under New Substances Program (US and Canada)	Not notified under New Substances Program (US and Canada)
Type of available information	Pchem, volumes, toxicity, leachability	Pchem, volumes, toxicity, industrial release	Pchem	-No information provided
Relevance to RCC	✓ - Good starting point since notified in both countries	x- Not a good selection in short-term since only notified to Canada	x- Little information submitted x- Likely touches on different legislative authorities (i.e., PMRA and FIFRA) because it may be a pesticide	x- No information submitted

Based on the responses/information provided with the nomination, MWCNTs were selected as the first nanomaterial for a case study. However, future work may include conducting additional case studies from the other nominated nanomaterials.

# Work Element 4: Commercial Information

- **Co-chairs**
  - Doug Green (Health Canada)
  - Ken Moss (US Environmental Protection Agency)

# Work Element 4 (Commercial Information) Objective

- Characterize existing commercial activities and identify gaps and priorities for future knowledge gathering for industrial nanomaterials
  - carry out an analysis of industrial nanomaterial uses in Canada and the United States
  - analyze commonalities and differences, identify gaps
  - develop mechanisms to gather information

# Commercial Information: Activities

- **August – November 2012:**
  - Share lessons learned from previous commercial data gathering activities
-  **November – May 2013:**
  - Countries share non-Confidential Business Information (CBI) information concerning industrial nanomaterials in the marketplace
  - Identify areas where information is limited
  - invite stakeholder comment and input to help address these gaps
- **May – November 2013:**
  - Initiate an assessment of industrial nanomaterial uses in Canada and the United States
- **Beyond November 2013:**
  - Complete assessment of industrial nanomaterial uses in Canada and the United States, and incorporate into summary report
  - Identify opportunities for and barriers to ongoing collaborations and regulatory alignment

# Progress to date

- Information shared on:
  - Voluntary surveys conducted for OECD Working Party on Manufactured Nanomaterials
  - Public information on commercial applications of nanomaterials in Canada and the US
  - United States Nanoscale Materials Stewardship Program (NMSP)
  - Nanomaterial notifications under Canadian and US New Substances programs
- Lessons learned:
  - Voluntary surveys likely underestimate marketplace due to limited participation
  - Some similarities between US and Canada in terms of commercial applications, but comparative analysis could be difficult because datasets are not comprehensive
  - Difficult to engage smaller and medium enterprises (significant commercialization activities expected to be within this sector)
  - US NMSP resulted in limited success – currently considering mandatory survey

# **Canada-US Regulatory Cooperation Council Nanotechnology Work Plan**

## **Moving Forward**

# Stakeholder Engagement

- Opportunity for stakeholders to help inform regulatory programs in Canada and the US and provide greater regulatory certainty
- Input from stakeholders will improve regulatory decision making in Canada and the US, and help prioritize regulatory and scientific research efforts
- Work collectively in protecting human health and the environment – ensure responsible development of nanomaterials in Canada and the US

# Next Steps

- **March 2013:** face-to-face workshop in Washington to discuss information collected to date and approaches moving forward
- **Spring 2013:** Conference call/webinar to discuss information gathered between countries and the path forward
- **Fall 2013:** Stakeholder consultation/workshop on results to date
- If you have any additional ideas or questions, please contact [rccnanoccr@ec.gc.ca](mailto:rccnanoccr@ec.gc.ca) (Canada) and [rccnano@epa.gov](mailto:rccnano@epa.gov) (US)