# Session 2: Overview of Progress Under the RCC Nanotechnology Initiative

# Nanomaterials under the RCC

- Nanomaterials may be regulated under many different acts in both countries (e.g., nanomaterials contained in consumer products, pharmaceuticals, pesticides, etc)

- The RCC Nanotechnology Initiative primarily focuses on nanomaterials considered to be new substances regulated in Canada and the US under the *Canadian Environmental Protection Act, 1999(CEPA*, 1999) and *Toxic Substances Control Act* (TSCA), respectively

- In Canada, any substance that is not on the Domestic Substances List (DSL) is classified as a new substance

- In the US, any substance that is not on the TSCA Inventory is classified as a new chemical

# Risk Assessment and Risk Management

Myriam Hill (Health Canada)

Todd Stedeford (US Environmental Protection Agency)

# Objective

To share best practices for assessing and managing the risks of industrial nanomaterials

# Comparison of Programs

| | TSCA (schedule 5.) | CEPA 1999 (NSNR) |
|---|---|---|
| Regulatory authority | - Pre-manufacture Notification Regulations | - New Substances Notification Regulations (Chemicals and Polymers) |
| Overall assessment process | -Involves input from several expert groups and assessment reports leading to initial review or standard review | -Each notification is assessed jointly by EC and HC evaluators |
| Assessment timeframe | - Ranges from 30 to 90 days<br>-Voluntary extensions can be granted. EPA can unilaterally extend for up to 90 days. | -Ranges from 5 to 75 days<br>-CEPA allows for one extension equivalent to the assessment period |
| New substance notification | -Need to notify only once (regardless of quantity produced) | -Notify based on volume thresholds (can be notified up to three times per notifier) |
| Regulatory triggers (entry level notification) | -None (Must notify prior to commencement)<br>- <10 000 kg/yr- Eligible for Low Volume Exemption (LVE) | - >100 or 1,000kg/year (dependant on whether the substance is listed on the US TSCA Inventory) |

# Comparison of Programs (Cnt'd)

| | TSCA (schedule 5.) | CEPA 1999 (NSNR) |
|---|---|---|
| Information requirements | - Includes requiring existing information in the possession of the submitter, parent company, or affiliated such as physical chemical properties, toxicology and environmental release data | - Includes prescribed information such as physical chemical properties, toxicology, exposure, and release<br>- Also includes requiring all information in possession of notifier |
| Is worker exposure part of assessment? | - Occupational exposure is usually the major focus of exposure assessment | - Consumer exposure is the major focus of CEPA assessments |
| Risk management options | -Consent orders<br>-Significant New Use Rules (SNUR)<br>-Ban or Ban pending testing | -Conditions of use<br>-Prohibition<br>-Ministerial request for additional information<br>-Significant New Activity Notices (SNAc) |
| # of notifications received | - Approximately 160 nanomaterial notifications | - Approximately 18 nanomaterial notifications |

# Comparative Case Study

A pilot project compared the risk assessments conducted by the two Programs for a specific Multi-Walled Carbon Nanotube (MWCNT)

- The pilot project concluded risk assessments in both countries:
  - Use similar methodologies;
  - Are conducted on a case-by-case basis; and
  - Employ conservative assumptions in the absence of data

- Risk management efforts in both countries:
  - Aim to reduce exposures; and
  - Allow for further assessment of nanomaterials in cases where there is increased environmental releases and/or direct human exposure

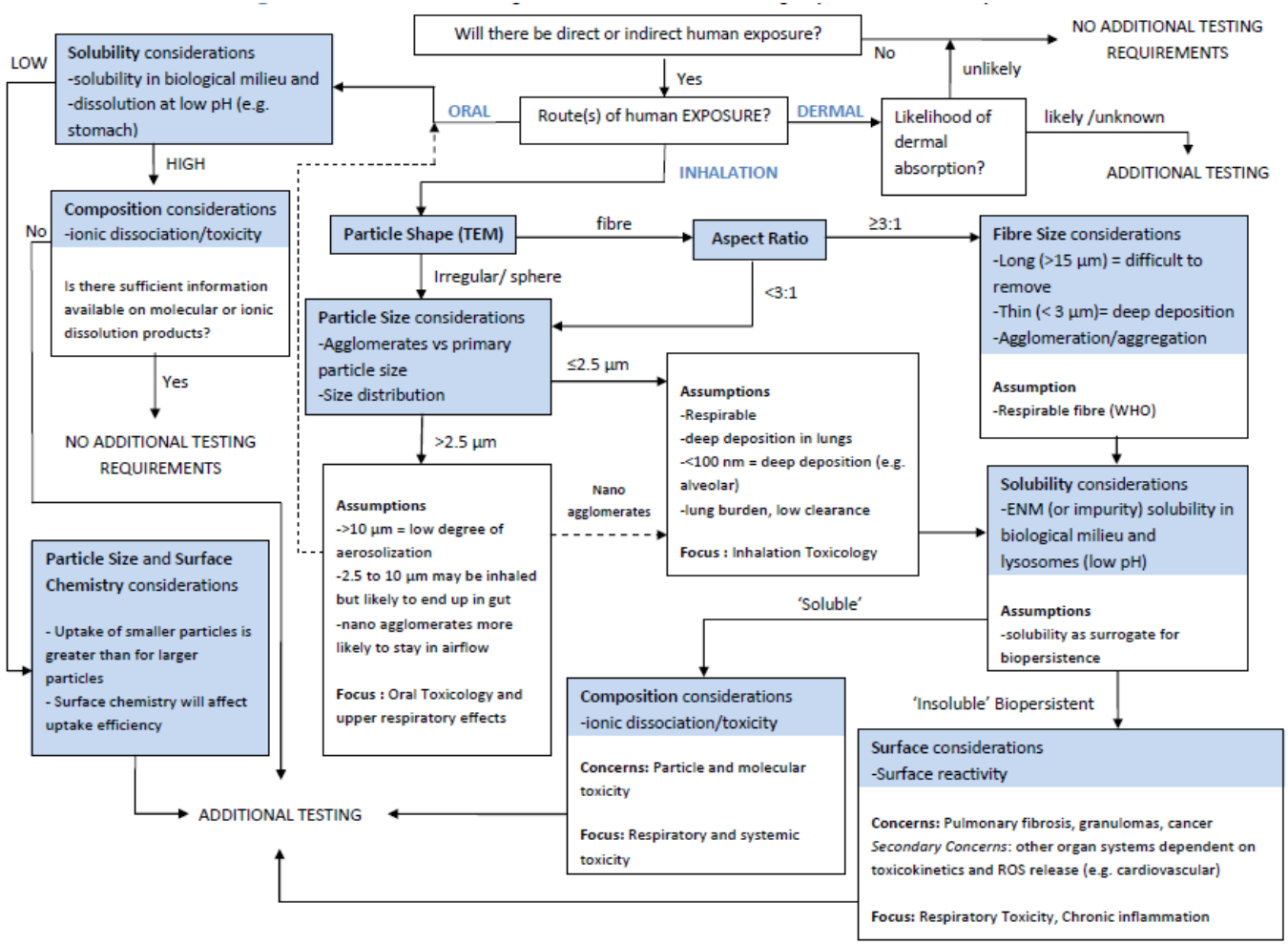
# Challenges and Opportunities in Nanomaterials Risk Assessment

- Challenges identified with respect to the risk assessment of nanomaterials included the lack of:
  - Standardized methods for identifying and characterizing nanomaterials;
  - Relevant physical-chemical properties for determining environmental fate and behaviour of nanomaterials;
  - Substance specific toxicity data; and
  - Suitable models for estimating properties, fate and effects

- The main differences between the risk assessments in Canada and the US occur due to foundational differences in their respective legislative and regulatory regimes, including differences in requirements, timelines and focus of assessments

# Common Approaches for Nanomaterial Risk Assessments

- An assessment framework for nanomaterials was developed for *human health endpoints:*



# Common Approaches for Nanomaterial Risk Assessments (Cnt'd)

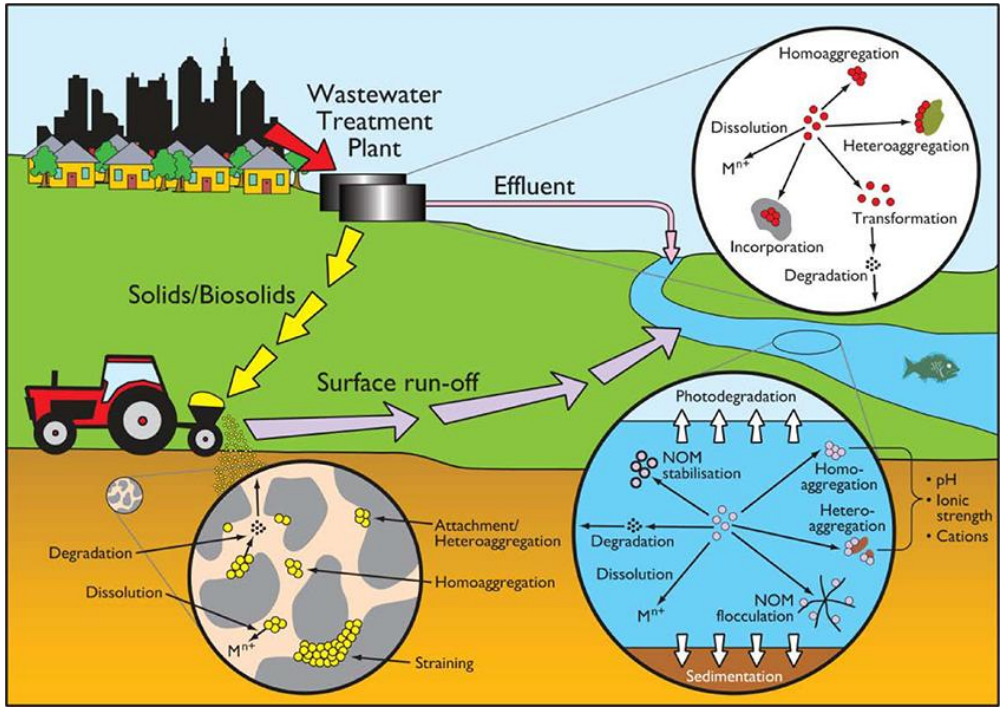
- Assumptions for evaluating *ecological fate and effects* were developed:

<u>Environmental Fate:</u>

- •NMs are likely present in all compartments
- •Log Kow not a useful predictor of bioconcentration
- •Releases will assume 100% partitioning to waters and biosolids

<u>Ecotoxicology:</u>

- •Uncertainty factors will be applied to account for interaction with organic matter
- •Utilize the OECD nano-specific guidance on sample preparation and dosimetry



# Main Findings

- The overarching principles for the assessment and management of nanomaterials are consistent between the two Programs

- Existing frameworks for chemicals are applicable, but may need to be adapted for nanomaterials
  - This finding is consistent with the recent OECD recommendation on the applicability of chemical frameworks for nanomaterials

# Moving Forward

- Canada-US collaboration is still needed to:
  - Develop common approaches and standard operational procedures (SOPs) for hazard and exposure assessment as science and regulatory knowledge becomes available
  - Align information requests used in regulatory decision making
    - E.g., when a substance is submitted in both countries, similar data requests can be expected to address similar concerns

# Priority-Setting

Yasir Sultan, PhD (Environment Canada)
Tracy Williamson, PhD (US EPA)

# Objective

To identify common criteria for determining characteristics of industrial nanomaterials of concern/no concern

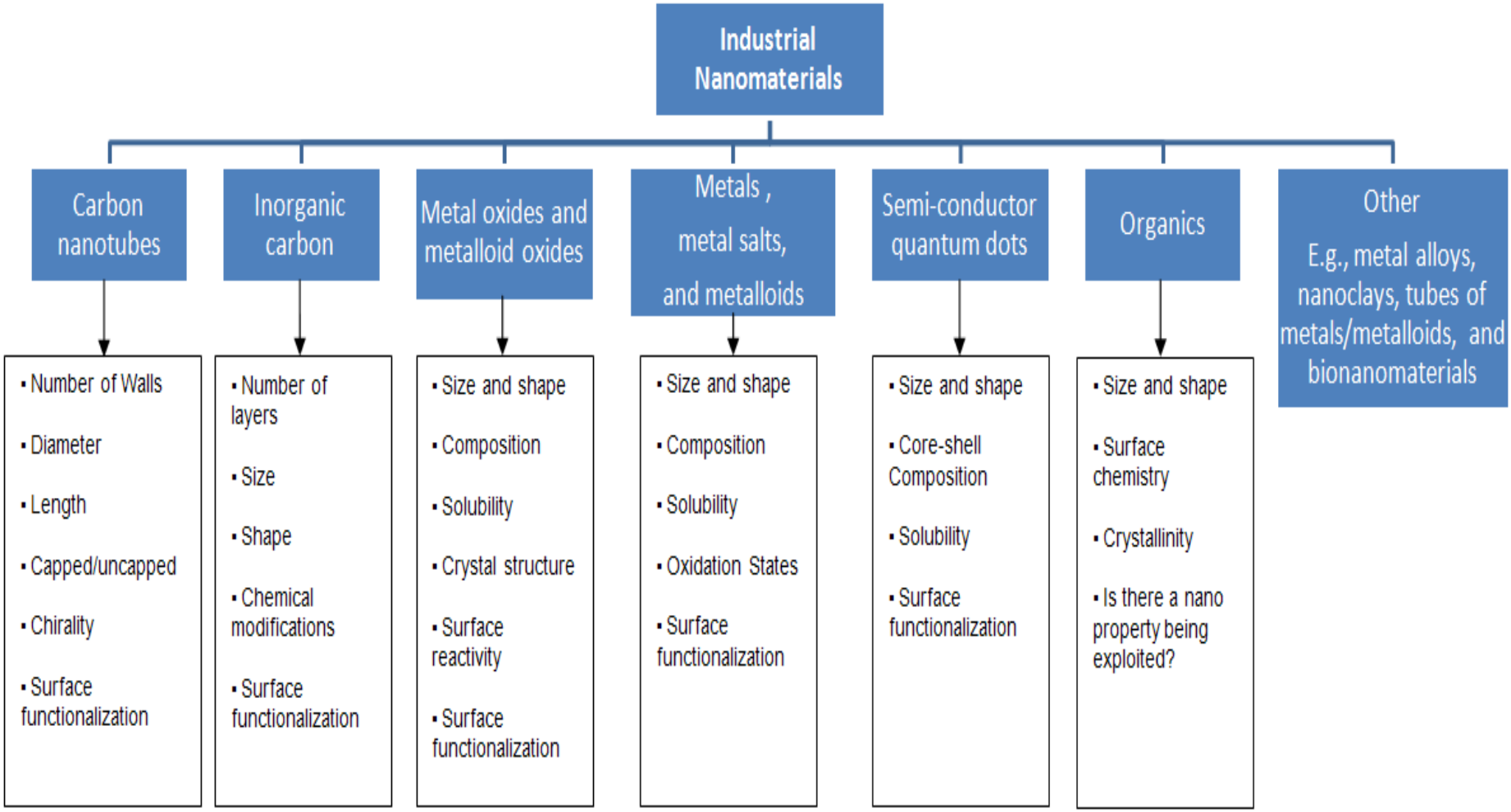
# Naming and Classifying Nanomaterials

- The Programs continue to discuss definition and terminology needs and participate internationally in the development of terminology, definitions, and nomenclature (e.g., ISO TC/229, OECD WPMN)

- A classification scheme based on chemical composition was developed, which:
  - Identifies the type of information typically needed to address additional nano-specific considerations
  - Provides a framework to consider utilization of information on similar substances (e.g., read-across/analogue)

- For this classification scheme to inform on hazard assessment -additional information is needed (e.g. identifying unique properties and their effects on organisms/mode-of-action)

# Classification scheme for nanomaterials

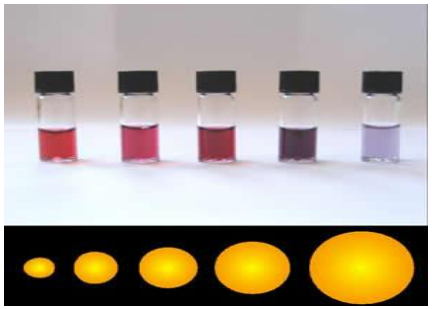


# Sorting Nanomaterials for Assessment

- The classification scheme will help the Programs sort nanomaterials that behave differently from their non-nano forms:
  - If a nanoscale substance *does not fall within* the scheme, it can be assessed as a traditional chemical;
  - If a nanoscale substance *falls within* the scheme, it may exhibit unique properties and will be assessed as a nanomaterial
- If a nanoscale substance does not fall within the scheme, the Programs may still assess it as a nanomaterial provided there is sufficient evidence that a unique property/phenomenon is being exploited
- This classification scheme should not be used to infer toxicological modes of action for nanomaterials as the science for this is still emerging

# Understanding the Hazards Associated with Unique Properties

- Globally, little is known about the potential toxicity associated with the unique properties of nanomaterials
  - e.g., bulk gold is inert and considered non-toxic, but nano-gold exhibits unique optical properties. The effects of these properties on organisms are unknown.



- Canada and the US will continue to investigate (e.g. through the OECD WPMN):
  - What are these unique properties?
  - How these properties interact with organisms?
  - What are the toxicological modes of action?

# Moving Forward

- Classification of nanomaterials based on similarities in chemical composition is a good starting point
- Work is needed to determine what makes two properties “sufficiently similar” to allow for read-across
- Refinement of the parameters will aid in the development of more precise subclasses, which will better guide the use of read across information in risk assessments
  - Additional scientific research and expert input is needed to further refine the parameters and the classes/subclasses
- Terminology, definitions, and nomenclature need to be developed with the international community

# Commercial Use Information

Doug Green (Health Canada)
Ken Moss (US Environmental Protection Agency)

# Objective

Characterize existing commercial activities and identify gaps and priorities for future knowledge gathering for nanomaterials

# Information and Lessons Learned were Shared from Previous Information Gathering Activities

- The Programs shared non-Confidential Business Information (non-CBI) concerning industrial nanomaterials in the market
  - Only aggregated CBI was shared in order to protect confidential business information
- Existing mechanisms to share CBI were identified that could be considered to allow for better informed risk assessments and risk management
- The lack of validation on the information available was identified as a major challenge from previous commercial data gathering activities, which limited its usefulness in RA/RM
- Volume information is needed to increase the precision of exposure scenarios in risk assessments and better focus risk management priorities

# Nanomaterial Uses in Canada and US were Compiled

- A use matrix was developed based on information from public sources/databases and regulatory submissions to the programs that correlates uses with specific types of nanomaterials
- This matrix was validated by industry stakeholders for its relevance to the Canadian and US marketplaces
- This use matrix, coupled with relevant exposure and release information, could be used to better inform risk assessments and focus risk management actions taken by the programs by helping to identify current and potential uses
- The use matrix is not, by itself, a prioritization list or a categorization of nanomaterials of concern/no-concern

# Snapshot of Nanomaterials Use Matrix

**Uses of Nanomaterials that are Commercialized or in Commercial Development**

1 - Carbon nanotubes
2 - Inorganic carbon
3 - Metal oxides & metalloid oxides
4 - Metals/metalloids
5 - Quantum dots
6 - Organics
7 - Other

| | | Coatings | Catalysts | Textiles | Paints | Rubbers | Epoxies | Electronics | Lighting | Adhesives | Lubricants | Plastics | Filtration | Pulp & paper products | Packaging | Sporting goods | Insulation | Emulsion stabilizers | Ceramics | Cements | Glass | Water Treatment | Batteries | Photovoltaics | Inks & pigments | Oil-processing fluids | Drilling fluids | Personal Care & cosmetics | Cleaning Products | Flame Retardants | Soil Remediation | Fuels | Pesticides | Medical Implants/Devices | Drugs/Drug Delivery | Magnetic resonance imaging | Food Contact Material | Consumer Applicances |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | **Carbon Nanotubes** | • | • | • | • | • | | • | | • | | • | • | | • | • | | | • | • | • | | • | • | • | | | | | • | | | | | | | | |
| 2 | **Graphene** | • | • | | • | | | • | | | | | | | | | • | | | | | | • | • | | | | | | • | | | • | | | | | |
| 2 | **Fullerenes** | • | • | | | • | | • | | | | • | | | | | • | | • | | | | • | • | | | | • | | • | | | | | | | | |
| 3 | **POSS** (Polyhedral oligomeric silsesquioxane) | • | | | • | | | | | | | • | | | • | | | | | | | | | | | | | | | • | | | | | | | | |
| 3 | **Modified silica** | • | | | • | • | | • | | • | | | | | | | | | | | | | | | | | • | | | | | | | • | | | | |
| 3 | **Aluminum oxide** | • | • | • | • | | | • | | | • | | • | | | | | | • | | | | • | | • | | • | | | | | | | | | | | |
| 3 | **Antimony tin oxide** | • | • | | | | | • | | | | | | | | | | | | | • | | • | | | | | | | | | | | | | | | |
| 3 | **Bismuth oxide** | • | | | | | | | | | | • | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | **Cerium oxide** | • | • | | | | | | | | | | | | | | | | | | | | • | | | | • | • | | | | | | | | | | |
| 3 | **Cobalt (II) oxide** | | • | | | | | • | | | | | | | | | | | • | • | | | • | • | • | | | | | | | | • | | • | • | | |
| 3 | **Copper (II) oxide** | • | • | | | | | • | | | | | | | | | | | | | | | | | • | | | | • | | | | • | | | • | | |
| 3 | **Indium Tin oxide** | • | | | | | | • | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | **Iron (III)/(II/III) oxide** | | • | | | | | • | | | | | | | | | | | • | | | | • | | • | | | • | | | • | • | | | • | • | | |
| 3 | **Magnesium oxide** | • | • | | | | | • | | | | | | | | • | | | | | | | | | | | | | • | | • | | | | | | | |
| 3 | **Manganese (II&III) oxide** | • | • | | | | | • | | | | • | | | | | | | | | | | • | | | | | • | | | | | | | • | | | |
| 3 | **Modified Iron oxide** | | | | | | | | | | | | | | | | | | | | | | | • | | | | | | | | | | | | | | |
| 3 | **Nickel (II) oxide** | • | • | | | | | • | | | • | • | | | | | | | | | | | • | • | • | | | | | | | | | | | • | | |
| 3 | **Silicon oxide** | • | • | | | • | | • | | • | | | | | | • | | | • | | | | | | | | | | | | | | | | | | |
| 3 | **Titanium dioxide** | • | | • | • | • | | • | | | | • | • | | • | | • | | | | • | • | | • | • | | • | | | | | | • | • | • | • | | |
| 3 | **Yttrium oxide** | • | | | | | | • | • | | | | | | | | • | | | | | | | | | | | | | | | | | | | | | |
| 3 | **Zinc oxide** | • | | • | • | • | | • | | | | • | | | • | | | | | | | | | | • | | • | | | | | • | | • | • | | |
| 3 | **Zirconium oxide** | • | • | | | | | • | | | | | | | | | | | • | | | | | | | | | | | | | | • | • | | | | |
| 4 | **Gold** | | • | | | | | • | | | | | | | | | | | | | | | | | | | | • | | | | | | • | • | • | | |
| 4 | **Silver** | • | • | • | | | | • | | • | | • | | | | | | | | | | • | | | • | | | • | • | | | | • | • | | | • | • |
| 5 | **Quantum dots** | | | | | | | • | • | | | | | | | | | | | | | | | • | | | | | | | | | | | | | | |
| 6 | **Other Organics** | • | | • | • | • | | | | • | | | • | | | | | | • | | | | | • | • | | | | | | | | | • | | | | |
| 6 | **Nanocellulose** | • | | • | • | • | | • | | • | | • | • | • | • | | • | • | | • | | • | | | • | • | • | | | | | | | | • | | | |
| 7 | **Modified Barium phosphate** | | | | | | | | | | | | | | | | | | | | | | | | • | | | | | | | | | | | | | |
| 7 | **Calcium carbonate** | | | | | • | | | | • | | • | | | | | | | | | | | | | • | | | | | | | | | | | | | |
| 7 | **Nanofibers (Incl. Classes 1-4)** | • | | • | | • | | • | | | | • | • | | • | | • | | • | | | • | • | | • | | | | | | • | • | | | | | |
| 7 | **Nanoclays** | • | • | | • | • | • | | | • | | | • | | • | | • | • | • | | | | | | | • | • | | • | • | • | | • | | | | | |

Last edited: September 18, 2013

# Main Findings

- Information gathered from public sources and stakeholder consultation demonstrated that PMN/NSN information received by the Programs is a good representation of the overall use profile in Canada and the US

- *Paints, coatings, and composites* are amongst the most significant uses of nanomaterials in Canada and the US

# Moving Forward

- The information in the Use Matrix should be used to develop joint generic release and exposure scenarios for nanomaterials, focusing on the most significant uses in Canada and the US

# Linkages

Yasir Sultan, PhD (Environment Canada)
Ken Moss (US EPA)

# Bringing it all together

- The outcomes should not be viewed in isolation
- The information gathered throughout the RCC Nanotechnology Initiative will be used to better inform risk assessment and risk management, for example:
  - It is probable that uses are similar between analogues within classes
  - By utilizing use information, better exposure/release scenarios could be developed
  - Analogues within classes will be used to increase weight-of-evidence for various aspects of risk assessments, such as physical-chemical properties, environmental fate, effects, and exposures
  - Using classes and use information to identify actual and potential uses and areas of concern

# Bringing it all together

Classification scheme to support use of read-across information and selection of analogues

Good knowledge of nanomaterial uses in Canada and the US

Use of particle screening framework and common assumptions to conduct human health and ecological risk assessments

Identified information gaps and refinement of approaches

More informed risk assessments and risk management measures

# Development of nanomaterial exposure scenarios

**Example of exposure scenario for industrial uses of paints, coatings and composites:**

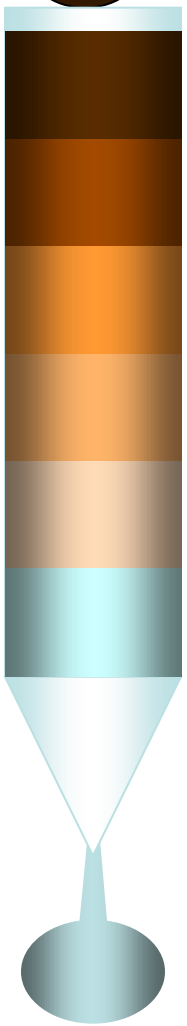
| | |
|---|---|
| Occupational exposure | Powders and aerosol have higher potential for exposure<br>Liquids are of lower potential for exposure |
| Environmental release (industrial) | Release estimates based primarily on volumes |
| Consumer exposure (use of finished product) | Low exposure once bound in the solid matrix<br>Consideration of classes? |
| Lifecycle releases | Limited knowledge, assessed on a case-by-case basis<br>Consideration of classes? |

# Annex

# 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 (TSCA)**

# Canadian Legislative Framework for Nanomaterials



| | |
|---|---|
| Feeds → | *Feeds Act* |
| Fertilizers → | *Fertilizers Act* |
| Pesticides → | *Pest Control Products Act* |
| Consumer Products → | *Canada Consumer Products Safety Act* |
| Novel Foods, Drugs and Medical Devices, Vet. Drugs → | *Food and Drugs Act* |
| **Industrial & Commercial Chemicals** → | ***Canadian Environmental Protection Act, 1999 (CEPA, 1999)*** |