

Canada's Experience with Chemicals Assessment and Management and its Application to Nanomaterials

European Chemicals Agency (ECHA) Topical Scientific Workshop:
Regulatory Challenges in Risk Assessment of Nanomaterials

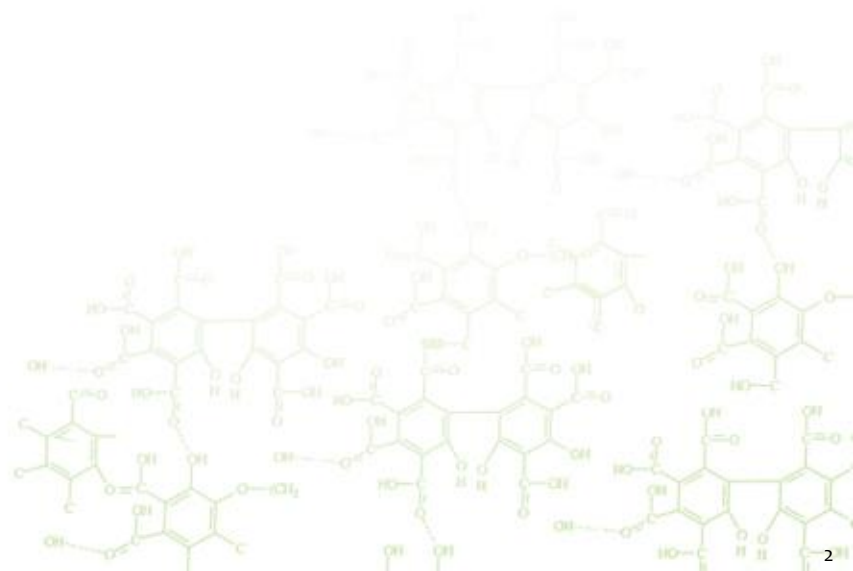
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Overview

- Canada's Framework for Chemicals Assessment and Management
- Canadian Perspectives on Scientific Challenges in Regulatory Risk Assessment of Nanomaterials

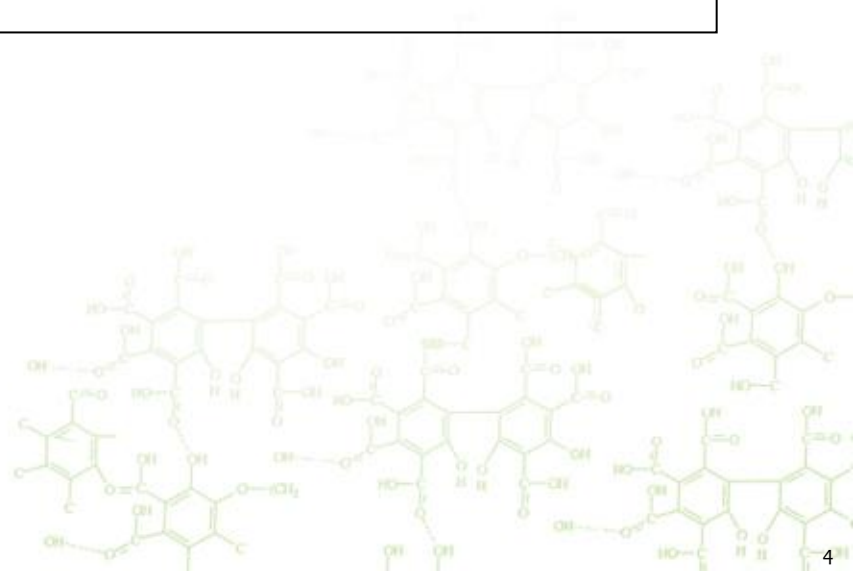


Purpose

- To share experiences from Canada's Chemicals Management Plan and their application to the risk assessment and risk management of nanomaterials
- To learn from REACH to inform Canada's domestic program
- To identify potential opportunities for alignment and cooperation

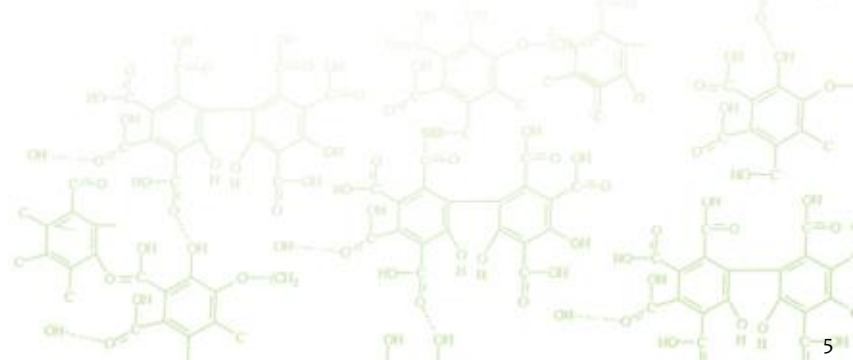
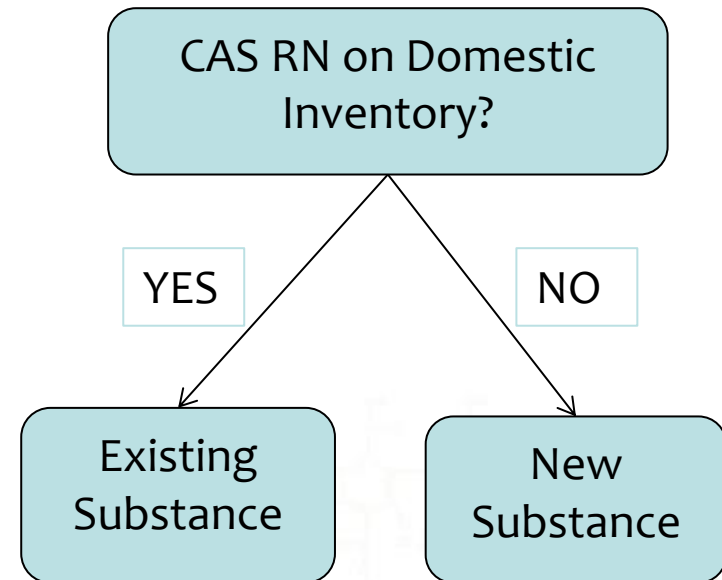


CANADA'S FRAMEWORK FOR CHEMICALS ASSESSMENT AND MANAGEMENT



Overall Chemicals Framework

- Under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), substances are classified as either new or existing based on whether they are listed on our domestic inventory (Domestic Substances List)
 - **New substances** are not listed on the domestic inventory and require a pre-market human and environmental risk assessments
 - **Existing substances** have been prioritized for post-market risk assessments



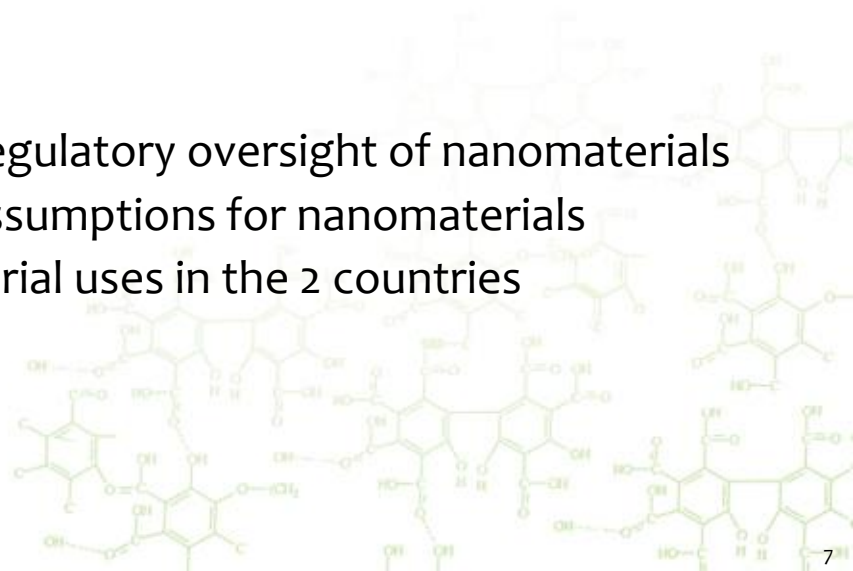
New Substances

- A notification must be submitted prior to manufacture or import of a new substance above trigger quantities
 - Trigger quantities (100 kg/year to 10,000 kg/year) are based on the quantity to be manufactured and/or imported annually
 - Increasing information requirements (e.g. physical-chemical properties, toxicology, exposure, release) as trigger quantities increase
- Environment Canada and Health Canada jointly conduct pre-market risk assessments and may impose control measures on notified substances if concerns are identified
 - e.g. Significant New Activity Notices, Ministerial Conditions, Ministerial Requests, or Prohibitions



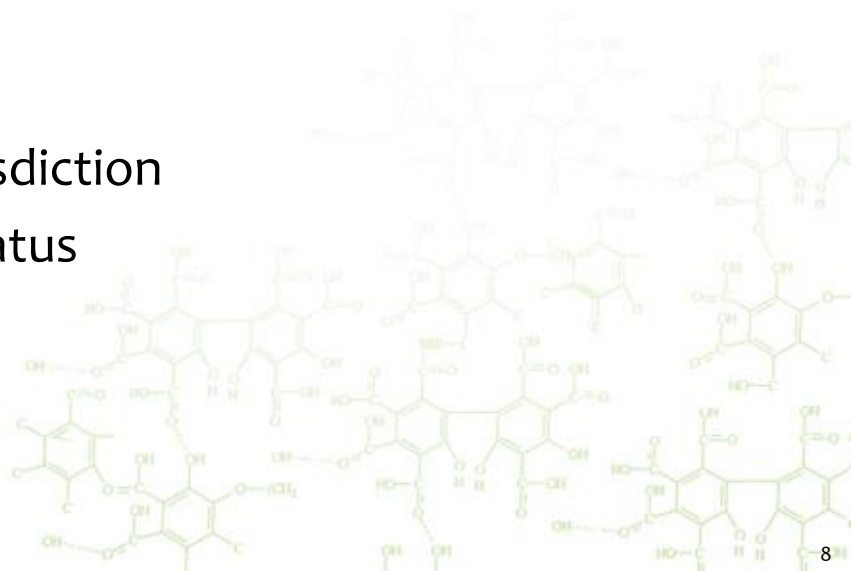
New Substances (continued)

- New nanoscale substances must also undergo pre-market risk assessments as required under the *New Substances Notifications Regulations*
- In order to examine similarities and identify common challenges in their new substances frameworks, Canada and the US recently completed a 2-year work plan on nanomaterials under the Regulatory Co-operation Council (RCC)
 - Outcomes included:
 - Common policy principles for the regulatory oversight of nanomaterials
 - Risk assessment approaches and assumptions for nanomaterials
 - Increased knowledge on nanomaterial uses in the 2 countries

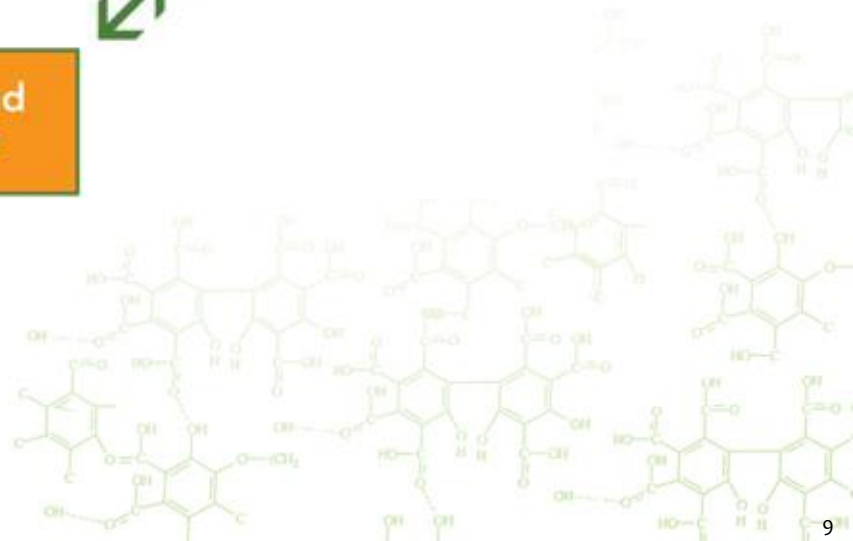


Existing Substances

- An existing substance is one that has been or is currently used in Canada as a commercial substance, or that is released into the Canadian environment on its own or as an effluent, mixture or contaminant
- Existing substances are prioritized for assessment based on a variety of feeders, such as:
 - Emerging science and monitoring
 - Results of a decision in another jurisdiction
 - New information on commercial status
 - New hazard information



CEPA (1999) Cycle



Evolution of Risk Assessment and Risk Management Approach in Canada

1980s – mid 2000s

Priority Substances List approach

In depth assessment of a limited number of priority substances

Number of assessments:

- 44 substances from 1989 to 1994
- 25 substances from 1995 to 2008

These assessments were extremely detailed, with a high level of information available; but were extremely time intensive, and only addressed a limited number of substances.

Since mid-2000s

Chemicals Management Plan

All existing substances were categorized, and approximately 4300 were identified for assessments

Number of assessments:

- CMP1 – approx. 1100 substances (2006 -2010)
- CMP2 – approx. 1500 substances (2011 - 2015)
- CMP3 – approx. 1700 substances (2016-2020)

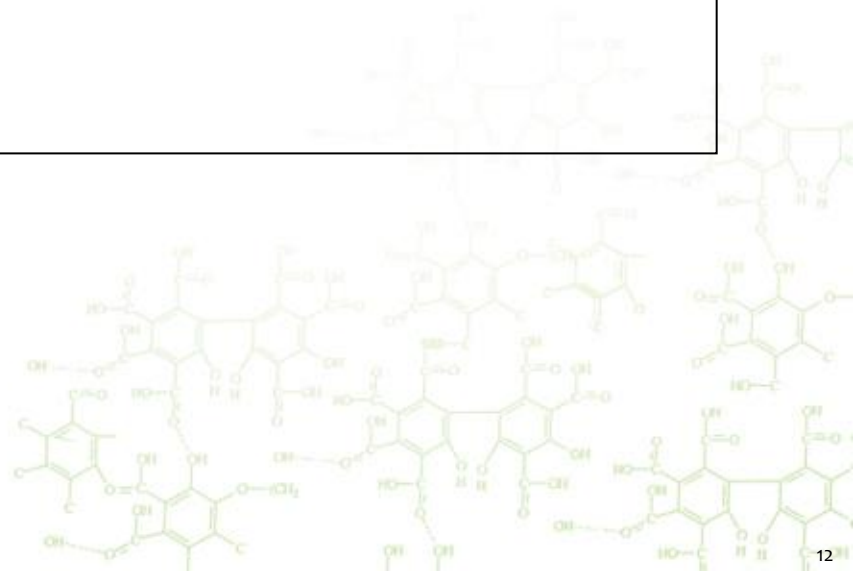
The CMP represented a paradigm shift towards a more rapid approach to address the legacy of chemicals in Canadian commerce. Significant emphasis is placed on stakeholder engagement. Emphasis on making regulatory risk assessment decisions based on best available information

Approach to Address Existing Nanomaterials

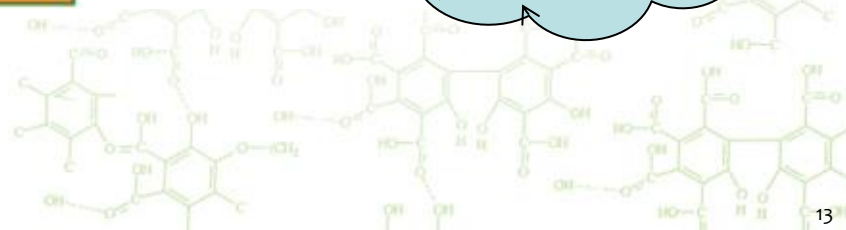
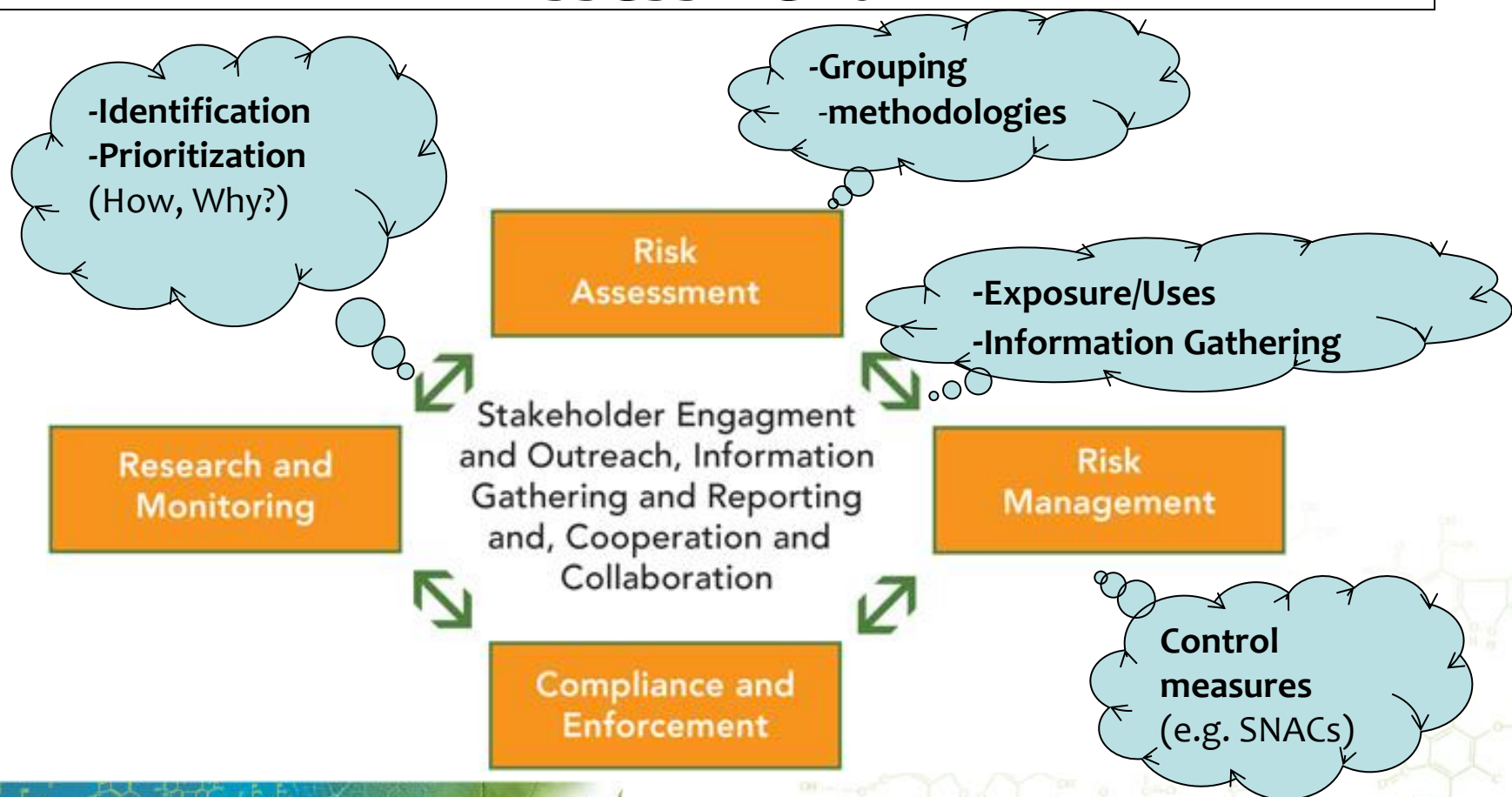
- Canada is now developing an approach to address the legacy of nanomaterials that are already in commerce in Canada, much like the Chemicals Management Plan
- The approach would include the following elements:
 - Validation of current understanding of status of nanomaterials on our domestic inventory
 - Development of a prioritization process for assessment of these nanomaterials
 - Examining priority nanomaterials for their potential impacts on the environment and human health
- Ideal opportunity to work with ECHA to share information and approaches on nanomaterial risk assessment



CANADIAN PERSPECTIVES ON SCIENTIFIC CHALLENGES IN REGULATORY RISK ASSESSMENT OF CHEMICALS AND NANOMATERIALS



Overview of Challenges in Nanomaterial Risk Assessment

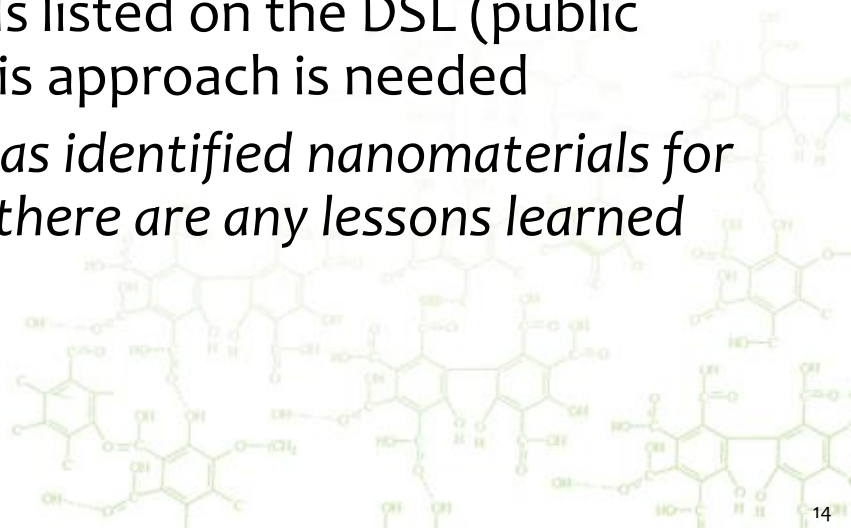


#1 – Identifying Nanomaterials

Challenge: Providing clarity on which nanomaterials are to be reported for regulatory review *is challenging without appropriate nomenclature and definitions*

- The Canadian regulatory program uses a policy definition based primarily on particle size and ‘unique’ properties to guide identification of nanomaterials.
- This approach was refined under the RCC to more clearly identify when a nanomaterial may exhibit unique properties
- As we begin to review nanomaterials listed on the DSL (public inventory), further refinement of this approach is needed

Canada is very interested in how ECHA has identified nanomaterials for the purposes of REACH reporting and if there are any lessons learned

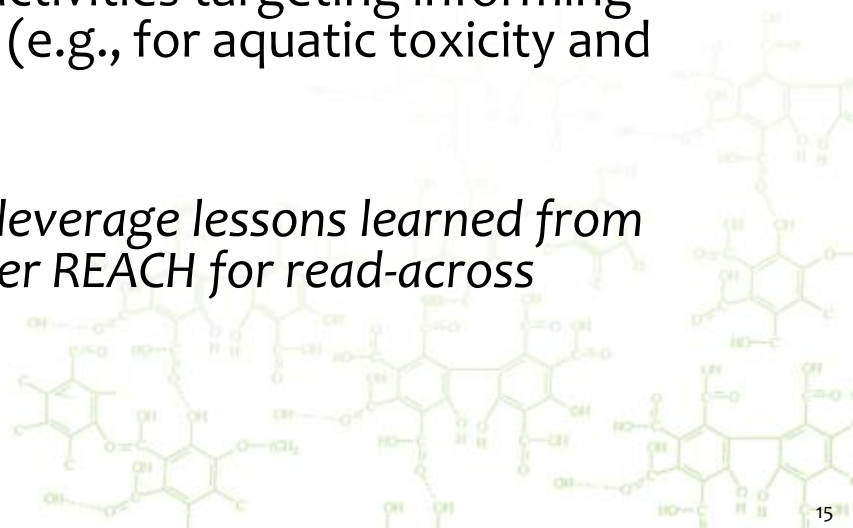


#2 – Grouping Nanomaterials for safety assessment end-points

Challenge: *Grouping nanomaterials according to safety end-points (e.g., toxicology) can increase efficiency and confidence while decreasing data gaps and uncertainties*

- Groupings have worked very well under the CMP for conventional chemicals both at the risk assessment and risk management stages
- Classification schemes, such as the one under the RCC and those discussed at the OECD WPMN Expert Meeting on Categories could be useful at various stages of risk assessment and risk management
- Canada has been engaged in research activities targeting informing grouping approaches of nanomaterials (e.g., for aquatic toxicity and environmental fate)

Canada would welcome the opportunity to leverage lessons learned from how nanomaterials have been grouped under REACH for read-across



Proposed RCC Classification Scheme based on Similarities in Chemical Composition

Industrial Nanomaterials

Class: Carbon nanotubes

Relevant Physicochemical parameters:

- Number of Walls
- Diameter
- Length
- Capped/uncapped
- Chirality
- Surface chemistry
- Surface modification

Class: Inorganic carbon

Relevant Physicochemical parameters:

- Number of layers
- Size
- Shape
- Chemical modifications
- Surface chemistry
- Surface modification

Class: Metal oxides and metalloid oxides

Relevant Physicochemical parameters:

- Size and shape
- Composition
- Solubility
- Crystal structure
- Surface chemistry
- Surface modification

Class: Metals, metal salts, and metalloids

Relevant Physicochemical parameters:

- Size and shape
- Composition
- Solubility
- Oxidation States
- Surface chemistry
- Surface modification

Class: Semiconductor quantum dots

Relevant Physicochemical parameters:

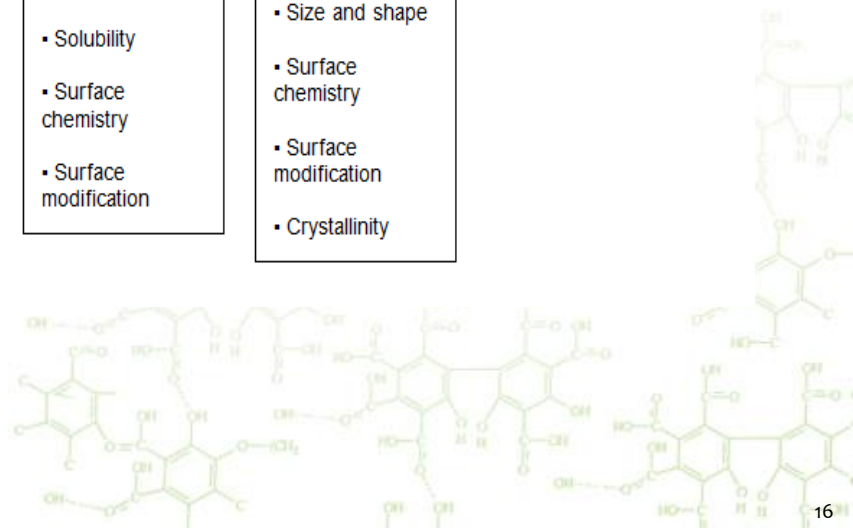
- Size and shape
- Core-shell Composition
- Solubility
- Surface chemistry
- Surface modification

Class: Organics

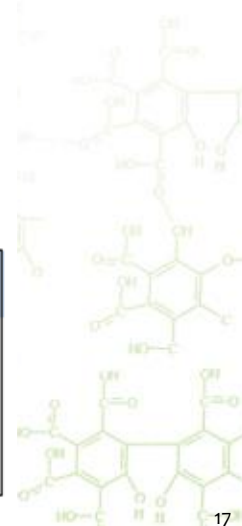
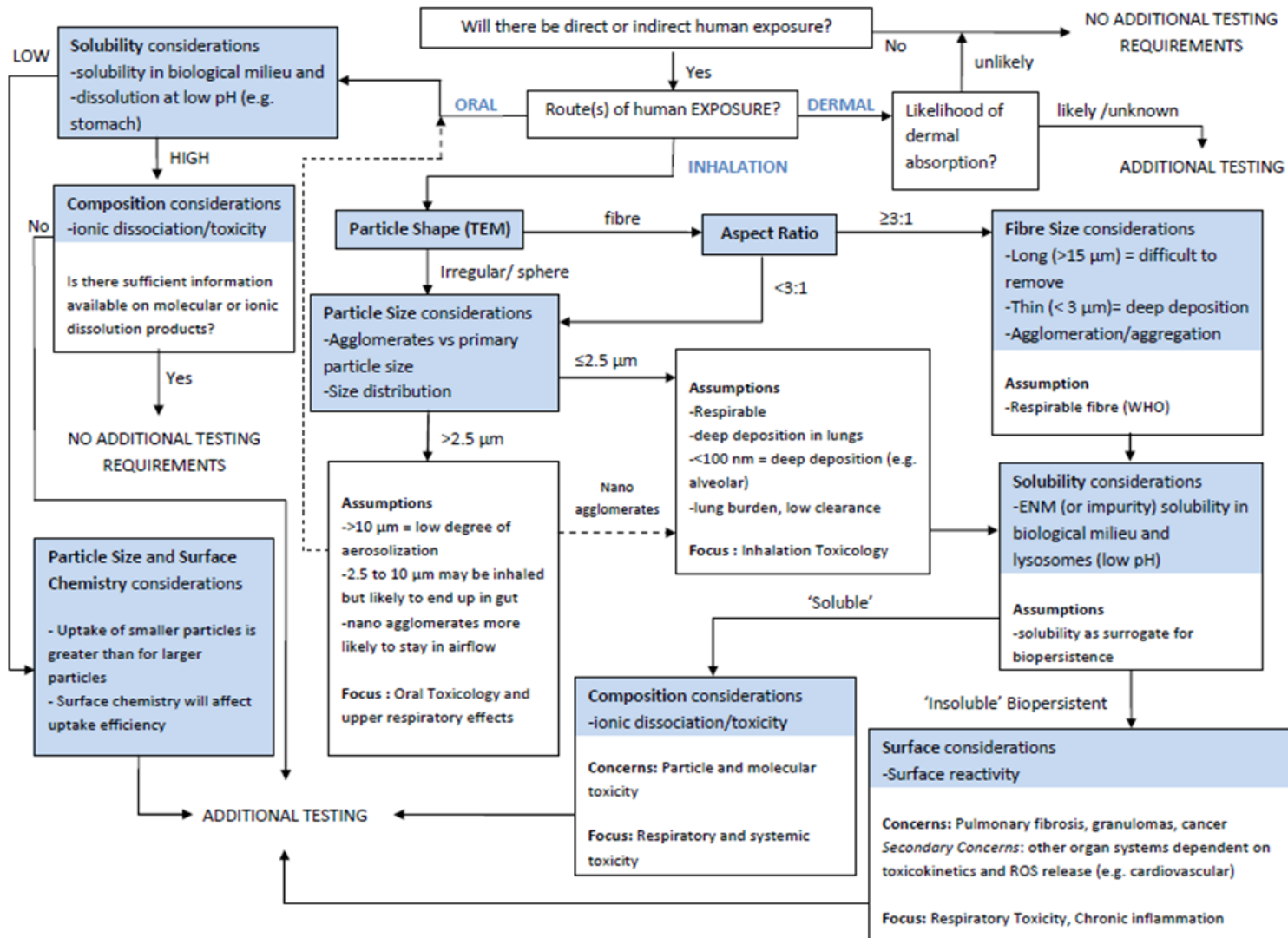
• Is there a nano property being exploited?

- #### Relevant Physicochemical properties:
- Size and shape
 - Surface chemistry
 - Surface modification
 - Crystallinity

Other classes
E.g., metal alloys, nanoclays, tubes of metals/metalloids, and bionanomaterials



Particle Screening Framework for Human Health Endpoints

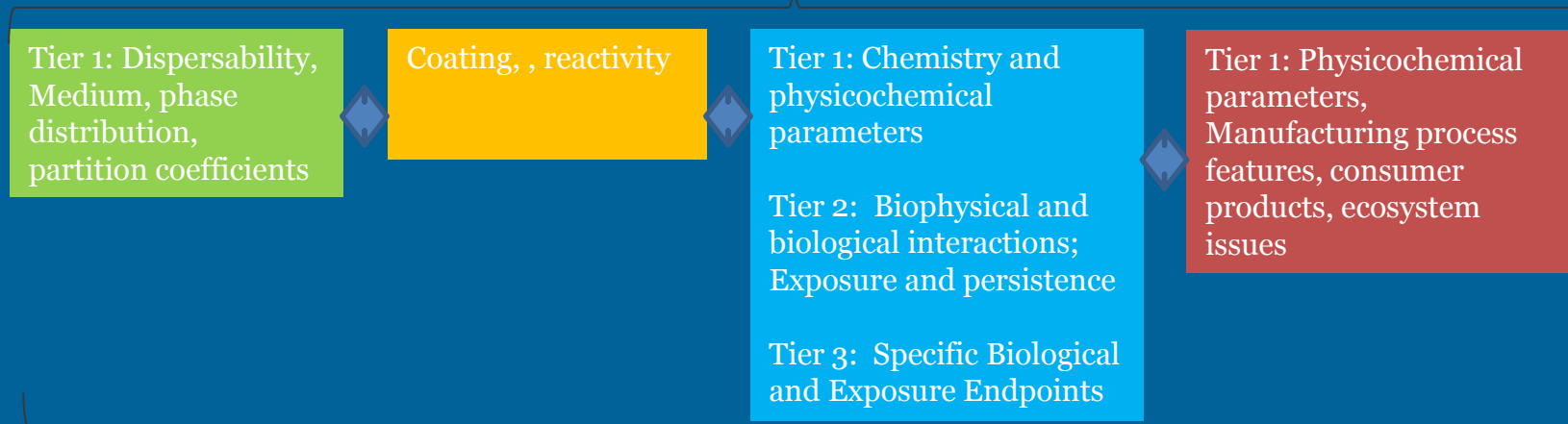




A proposal for a nano-RA categorization



Intrinsic characterization of parameters (size, shape, crystallinity, etc)



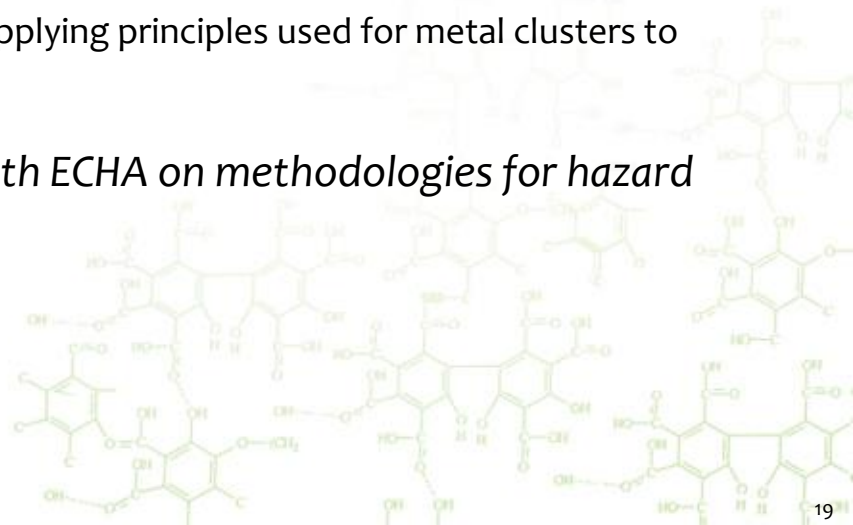
Extrinsic parameters: Surface chemistry, Dissolution, stability in relevant media, effect of coating, (bio)persistence,

#3 – Risk Assessment Methodology

Challenge: The risk assessment methodology used for nanomaterials needs to be scientifically justifiable and must represent real behaviours

- There are few tools available to regulators to assist in predicting environmental and population level exposures
- Under the Canada-US RCC, both countries discussed risk assessment methodologies for nanomaterials and associated uncertainties/gaps
- Canada chairs the OECD WPMN SG-AP, a group focused on looking at risk assessment approaches for nanomaterials
- Canada has experience with metal-based chemicals under the CMP, which could be relevant in some nanomaterial risk assessments (i.e., when effects are due to release of ions)
 - Canada continues to support research looking at applying principles used for metal clusters to nanomaterials

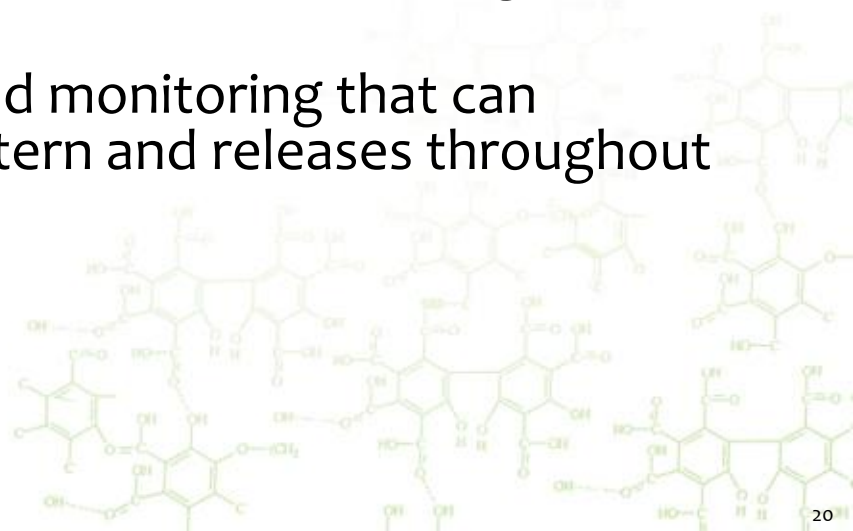
Canada would welcome the opportunity to work with ECHA on methodologies for hazard assessment of nanomaterials



#4 – Information Gathering

Challenge: Information is needed to understand use-patterns of nanomaterials in Canada to inform exposure assessments

- Relevant exposure to Canadians and the environment is an important element of chemicals risk assessments
- Under the RCC, Canada and the US qualitatively mapped out the types of nanomaterials in commerce with stakeholders
- There is little quantitative information on use-patterns of nanomaterials in commerce beyond that received through pre-market notifications
- We continue to look for research and monitoring that can quantitatively demonstrate use-pattern and releases throughout the substance life-cycle



Conclusions

- There are many scientific challenges with the regulatory risk assessment of nanomaterials
 - Canada has gained many helpful experiences from its Chemicals Management Plan which it plans to learn from and build on to address existing nanomaterials
 - Canada has gained many insights through the RCC Nano initiative
 - The OECD WPMN is a good venue to develop harmonized approaches for risk assessment, as well as information gathering and research needs
- Canada is interested in engaging international partners to inform a Canadian approach for assessing nanomaterials our public inventory
- Canada will continue to rely on bilateral (e.g., ECHA, US, Australia) and multilateral (e.g. OECD) initiatives to ensure consistency, transparency, and validity of risk assessments and risk management approaches

