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# Challenges in Regulating Nanomaterials under the *Canadian Environmental Protection Act, 1999*

**Nanomaterial Health & Safety Forum  
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# Overview

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- Current Regulatory Regime for “New Substances” under CEPA 1999
- Challenges with Nanomaterials
- Proposed Regulatory Framework for Nanomaterials
- Next Steps

# Current Regulatory Regime for New Substances under CEPA 1999

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- Part 5 of CEPA 1999:
  - Requires the notification and assessment of “new” substances (including nanomaterials) prior to import into or manufacture in Canada
    - Under CEPA, a new substance is a substance not listed on the Domestic Substances List (DSL)
  - Provides for the assessment of “existing” substances (including nanomaterials) already on the Canadian market
    - No specific data requirement or timeframe
  - Assessments objective: to determine whether the substance poses or may pose a risk to the environment or human health

# Regulation of Nanomaterials under Part 5 of the CEPA 1999

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- New Nanomaterials (not listed on the DSL)
  - Subject to the same regulatory requirements as new chemicals and polymers under the *New Substances Notification Regulations (Chemicals and Polymers)* (NSNR)
  - Current policy considers the nanoscale form of a substance on the DSL to be a “new” substance if it has a unique structure or molecular arrangement
- Existing Nanomaterials
  - Current policy considers substances listed on the DSL whose nanoscale forms do not have unique structures or molecular arrangements to be “existing substances”

# Challenges with the Regulation of Nanomaterials

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- Science Issues
  - Limited test data available for nanomaterials to predict and understand potential health and environmental impacts
  - Environment Canada (EC) and Health Canada (HC) are supporting and sponsoring the development of data within government and academic research facilities, as well as participating in a global research program through the OECD
  - Results of this research will assist in the risk assessment of nanomaterials as well as inform the federal government on regulatory oversight needed

# Challenges with the Regulation of Nanomaterials

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- Regulatory Issues
  - CEPA lacks specific provisions and/or regulations for nanomaterials
  - The absence of a nomenclature system specific to nanomaterials presents challenges for identifying nanomaterials for assessment
  - Nanomaterials may be imported or manufactured in volumes below trigger quantities for notification under the NSNR
  - Information requirements in the NSNR are tailored to chemicals and polymers, and may not be adequate for nanomaterials

# Proposed Regulatory Framework for Nanomaterials under CEPA 1999

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- Released in September, 2007 by EC and HC
- Subject to multi-stakeholder consultations
- Outlines a phased process to developing the necessary regulatory infrastructure to provide oversight of nanomaterials under CEPA 1999



# Proposed Regulatory Framework – Phase 1

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- Inform potential notifiers of their regulatory responsibilities
  - EC and HC Issued and advisory note on the subject in July, 2007
- Work with international partners to develop relevant scientific information and tools:
  - Through OECD, developing data, test methods, and guidance covering a broad spectrum environmental, health and safety issues
  - Through ISO, development of terminology, nomenclature, standard methods for material characterization, as well as development of reference materials
- Develop initiatives to gather information from industry on the uses, properties and effects of existing nanomaterials
  - EC planning to issue a survey in the coming months to gather information on nanomaterials already on the Canadian market
  - Industry Canada will be updating their database of products containing nanomaterials
- Consider the type of amendments to the Act and Regulations that could be needed

# Proposed Regulatory Framework – Phase 2

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- Resolution of terminology and nomenclature by ISO
  - EC is leading a task group on the development of a nomenclature model for nanomaterials
- Propose data requirements specific to nanomaterials under the NSNR
  - results of the use pattern survey and the global testing program will inform the Departments on the nature of the amendments needed
- Consider use of the Significant New Activity Provisions of CEPA 1999 to require notification of nanoscale forms of substances already on the DSL
  - to ensure re-notification of substances when manufactured at the nanoscale

# Next Steps

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- Issue use pattern survey
  - To gather information from Canadian industry on the uses, properties and effects of existing nanomaterials
- Participate in the development of a Federal Government single window nanotechnology website known as the “Nanoportal”
  - To enhance communication with regulatees and the public
- Increase support in research on the environmental fate and effects of nanomaterials in the Canadian environment
  - to inform amendments to the Regulations and Act
- Continue participation in global effort to develop scientific information and tools to better assess potential risks to the environment and human health