PROPOSED REGULATORY FRAMEWORK FOR NANOMATERIALS UNDER THE 
CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

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Environment Canada       Health Canada
Environnement Canada      Santé Canada
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INTRODUCTION

Environment Canada and Health Canada have developed a proposal for a regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999. Under the provisions of this legislation, the Ministers of the Environment and Health are required to conduct environmental and human health risk assessments and manage appropriately any risks arising from industrial chemical substances entering the Canadian market. Stakeholders from industry, non-governmental organizations, and other interested parties are invited to provide feedback on the proposed approach to developing a regulatory framework as well as to consider the options for gathering information on industrial nanomaterials as a part of the first phase.

Nanotechnology is a rapidly emerging field described generally as the control and structuring of matter at dimensions typically between 1 and 100 nanometres to create materials, devices, and systems with fundamentally new properties and functions. Nanoscale chemical substances, or nanomaterials, behave differently from their macroscale counterparts, exhibiting different mechanical, optical, magnetic, and electronic properties. As a result of such novel properties, nanomaterials are anticipated to have applications addressing a wide range of issues including health and the environment. The novel properties of nanomaterials, however, may also give rise to new exposures and effects which need to be assessed for their potential impacts on human health and the environment. It is incumbent on Environment Canada and Health Canada to develop a regulatory framework under the Canadian Environmental Protection Act, 1999 which enables the responsible introduction of nanomaterials to Canada through the scientific assessment and appropriate management of the potential risks.

The proposal for the development of a responsible regulatory framework under the Canadian Environmental Protection Act, 1999 consists of two phases as international and domestic activities progress. Canada is involved with the activities of the Organization for Economic Co-operation and Development and the International Organization for Standardization. The federal Science & Technology community is coordinating efforts within the government of Canada to address regulatory science issues. These activities will inform the development of a regulatory framework in a progressive manner which builds a foundation of knowledge through collaboration with industry and the public.

This document provides background information on nanomaterials and the Canadian Environmental Protection Act, 1999 as well as information on the proposal for developing an effective regulatory framework for nanomaterials. The following sections contain:

- A brief overview of the science and impacts of nanomaterials;
- The role of the New Substances Program in conducting risk assessments;
- The proposed approach for a regulatory framework for nanomaterials under the Canadian Environmental Protection Act, 1999;
- Options for information gathering initiatives; and
- Path forward for Government and stakeholders.
BACKGROUND

BASIC SCIENCE OF NANOMATERIALS

The field of nanotechnology finds its roots in physics, chemistry, biology, and engineering and is described generally as the manipulation of matter at the scale of typically 1 to 100 nanometres to create new and innovative materials, devices, and systems. One nanometre is equal to one billionth of a metre. By comparison, the diameter of human hair is about 100,000 nm and a red blood cell measures approximately 10,000 nm (US EPA, 2007). At these dimensions, chemical substances exhibit properties different from their macroscale counterparts. For example, nano-gold exhibits dramatic changes in properties and colour with only slight changes in size (Science Daily, 2004).

Nanomaterials can also be formed at the nanoscale in either 1 dimension (chips, sheets), 2 dimensions (tubes, rods) or 3 dimensions (particles, spheres, cubes). The properties observed in nanomaterials are the result of several unique material characteristics, including confinement and high surface area. Confinement occurs in the formation of a metallic nano lattice structure where the atoms are squeezed much closer together than one would observe in a standard bulk metal lattice. In this state of confinement, the atoms strain against forces of repulsion and generate some of the unique properties that we observe in metallic nanomaterials. Concerning high surface area, we are familiar with the high surface area in the context of activated charcoal and its ability to absorb contaminants. Nanoparticles, such as nanotubes, and metal oxides likely have substantially higher surface areas than their counterparts, and this feature also induces different material behaviours.

The changes in the mechanical, optical, magnetic, and electronic properties of nanoscale chemical substance, or nanomaterials, give rise to their potential use in a broad range of applications including those which can address human health and environmental issues. For example, iron nanoparticles are being studied for use in contaminated site remediation as a more effective and efficient scavenger of contaminants due to an increased number of reactive sites relative to the size and volume of the nanoparticles (Varanasi, Fullana, & Sidhu, 2007). Nano-silver particles exhibit anti-bacterial properties and are being blended in household paints which are available in the consumer market (Nano Acceleration Network, 2006).

IMPACTS OF NANOMATERIALS

By the year 2015, an estimated $1 trillion worth of products worldwide will incorporate nanotechnology (Roco and Bainbridge, 2001). Some nanomaterials are currently in use with many consumer products available which utilize nanotechnology or nanomaterials in some manner (Woodrow Wilson International Center for Scholars, 2007). The Canadian market for nanotechnology is increasing with more funds being directed towards research and development (Canadian Broadcasting Corporation, 2007).

While the novel properties of nanomaterials may lead to new innovations, these same properties may give rise to new risks. For example, the physical size of nanomaterials may facilitate entry
into the body of organisms and the crossing of cellular membranes. The high surface area to
volume ratio of nanomaterials can result in a greater number of reactive sites, thus increasing the
potential for interaction with other entities. Additionally, the electronic properties of
nanomaterials may interfere with normal cell function. There is, however, a limited
understanding of the potential impacts and further research is needed.

In order to regulate nanomaterials effectively, a better understanding is needed of the properties,
behaviour, and effects of nanomaterials. Environment Canada and Health Canada are proposing
an approach to the development of a regulatory framework under the mandate of the Canadian
Environmental Protection Act, 1999 to address nanomaterials in a manner which ensures the
responsible introduction of nanomaterials to the Canadian market through a program which
scientifically assesses and appropriately manages any potential risks.
CEPA 1999 AND THE NEW SUBSTANCES PROGRAM

The Canadian Environmental Protection Act, 1999 (CEPA 1999) is in place to contribute to sustainable development through pollution prevention and the protection of the environment and human health. Part 5 of CEPA 1999 establishes a legal regime for the assessment and management of chemicals and polymers which includes provisions for new and existing substances as well as information gathering and assessment powers. Under the provisions of CEPA 1999, the Ministers of the Environment and Health are required to conduct environmental and human health risk assessments and manage appropriately any risks arising from chemical substances entering the Canadian market.

The scope of CEPA 1999 includes the risk assessment and risk management of new and existing commercial and industrial substances. Other applications of nanomaterials, such as pesticides and pharmaceuticals, are addressed under other appropriate legislation (e.g., Pest Control Products Act, Food and Drugs Act). The Food and Drugs Act, however, does not provide the authority for addressing potential environmental and human health impacts from environmental exposure to substances and CEPA 1999 is used to address this regulatory oversight.

The New Substances Program is responsible for conducting risk assessments and administering appropriate risk management, when necessary, of chemical substances under the authority of the New Substances Notification Regulations (Chemicals and Polymers) (NSNR). Prior to a chemical substance being introduced to the Canadian market, companies are required to submit a notification to Environment Canada and Health Canada following prescribed information requirements under the NSNR.

Under the current regulatory framework, an “existing” substance is any chemical or polymer listed on the Domestic Substances List (DSL). The DSL is a compilation of all known substances that were in Canadian commerce between 1984 and 1986 or that are added to the DSL in accordance with CEPA 1999. A “new” chemical substance is any substance not listed on the DSL and is subject to notification to the government for assessment. The New Substances Notification Regulations (Chemicals and Polymers) (NSNR), specify the information to be submitted if a new substance is intended for import to or manufacture in Canada. (Environment Canada, 2007a).

At present, there is no definitive system of nomenclature for nanomaterials; however, over the next year Canada will be working with other countries under the auspices of the International Organization for Standardization (ISO) to develop a nomenclature system specific to nanomaterials. Once in place, this nomenclature system will simplify the task of determining whether a particular nanomaterial is new or existing under CEPA 1999.

Until a nomenclature system is established, Canada has issued an advisory note describing new and existing nanomaterials under the current regulations (See Appendix A, Environment Canada, 2007b). Substances listed on the DSL whose nanoscale forms do not have unique structures or molecular arrangements are considered “existing”. The nanoscale form of a substance on the DSL is considered a “new” substance if it has unique structures or molecular arrangements.
Nanomaterials present challenges to the current regulatory framework under CEPA 1999 because their novel properties may give rise to new effects and behaviours which may lead to impacts on human health and the environment. The current data requirements for “traditional” chemicals and polymers may not be appropriate to permit adequate risk assessments of nanomaterials. Therefore, Environment Canada and Health Canada are proposing an approach for the development of a regulatory framework for nanomaterials under CEPA 1999.
PROPOSED APPROACH FOR A REGULATORY FRAMEWORK FOR NANOMATERIALS

A regulatory framework for nanomaterials needs to be developed in a way that is scientifically robust and harmonizes with the outcomes of international efforts. Environment Canada and Health Canada are proposing the development of a regulatory framework for nanomaterials consisting of two phases of implementation based on shorter and longer term objectives.

- Phase 1 (started fall 2006)
  a. Continue work with international partners to develop scientific and research capacities (OECD, ISO).
  b. Inform potential notifiers of their regulatory responsibilities under the current framework.
  c. Develop initiatives to gather information from industry on the uses, properties, and effects of nanomaterials.
  d. Consider whether amendments to CEPA 1999 or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

- Phase 2 (starting 2008)
  a. Resolution of terminology and nomenclature by ISO TC229.
  b. Consider establishing data requirements under the NSNR specific to nanomaterials.
  c. Consider the use of the Significant New Activity (SNAc) provision of CEPA 1999 to require notification of nanoscale forms of substances already on the DSL.

Phase 1a: Work with International Partners

The importance of a responsible regulatory framework is recognized not only in Canada but also in the international regulatory community. Efforts have been initiated to ensure coordination and encourage collaboration on the underpinning scientific issues which will meet the needs of all regulatory programs. International efforts towards understanding the properties, effects, and behaviours of nanomaterials are being led primarily by the Organization for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO). (See Appendix B for more information). Canada is in a position to inform the development of a domestic regulatory framework by drawing on the experiences and expertise of other countries.

Phase 1b: Communication with Industry and the Public

The New Substances Program is preparing communication materials to inform industry and the general public of nanotechnology and nanomaterials issues including information gathering initiatives and regulatory responsibilities under CEPA 1999 for manufactured or imported nanomaterials. Communication will be in the form of advisory notes, factsheets, web postings, public presentations, and multi-stakeholder meetings. Environment Canada is also working with Industry Canada on several projects to develop lists of potential nanotechnology related firms and associations in Canada.
Phase 1c: Information Gathering Initiatives

The purpose of information gathering initiatives is to promote the submission of data from industry to regulatory programs in order to inform the development of effective regulatory frameworks. Due to limited information on use patterns, effects, and behaviour of nanomaterials, governments worldwide are implementing both voluntary and mandatory schemes to obtain data from industry and build a foundation of knowledge on nanomaterials. Environment Canada and Health Canada are examining a number of options toward the development of an effective information gathering program. See the section below on information gathering initiatives for more details on the proposed initiatives.

Phase 1d: Legislative Amendments

Since the current regulatory framework for new substances does not address nanomaterials specifically, amendments to CEPA 1999 and the NSNR may be considered in order to accommodate any necessary requirements to ensure risk assessment and risk management can be conducted effectively. Changes to CEPA 1999 may address emerging technologies, such as nanotechnology, by providing the authority to require the notification and assessment of substances associated with those emerging technologies, in a manner similar to the New Substances provisions of CEPA 1999. Another possible amendment would be to the definition of “substance” under section 3 of CEPA 1999 to more clearly include nanomaterials.

Phase 2a: Terminology and Nomenclature

Through the efforts of the ISO TC229, establishment of standard terminology and a standard nomenclature system is targeted for the end of 2008. Resolution of this matter will benefit regulatory programs by allowing for unique descriptors allowing nanomaterials to be distinguished from one another. This would simplify the use of regulatory instruments such as the Domestic Substances List, Significant New Activity notices, and Ministerial Conditions.

Phase 2b: Data Requirements for Nanomaterials

Amendments to the NSNR may be needed to prescribe data requirements specific to nanomaterials. The current range of data requirements for chemicals and polymers may not be suitable for nanomaterials and other endpoints may need to be considered (e.g., agglomeration, surface functionalization). Furthermore, current test methods may need to be modified and new test methods may need to be developed to accommodate nanomaterials. Various technical groups, including within the OECD and ISO, are examining the applicability of current test methods to nanomaterials.

Phase 2c: Significant New Activity (SNAc)

A Significant New Activity (SNAc) Notice is a notice describing, by inclusion or exclusion, a significant new activity that results or may result in:

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• a significantly greater quantity or concentration of the substance in the environment; or
• a significantly different manner or circumstances of exposure to the substance.

A SNAc Notice may be issued for a substance if there is a suspicion that a significant new activity in relation to the substance may result in the substance becoming “toxic” under CEPA 1999 (Environment Canada, 2007c).

For substances which are already in commerce, if there is a suspicion that the nanoscale form may pose a risk, Environment Canada and Health Canada can deem the nanoscale form of an existing substance as a significant new activity. The SNAc provision could be used to compel notification of the nanomaterial.
INFORMATION GATHERING INITIATIVES

Many countries have implemented or plan to implement information gathering schemes to obtain basic knowledge ranging from use patterns to effects data. The information gathered through these initiatives is for the purpose of directing the development of regulatory frameworks and the undertaking of preliminary risk assessments. Environment Canada and Health Canada are considering two options for obtaining information from industry: a voluntary information gathering program and a mandatory information gathering program under the authority of CEPA 1999.

Both a voluntary and a mandatory program would target nanomaterials which are deliberately manufactured or engineered. The types of information requested would include substance identification; use patterns, including applications and quantities of use; physical-chemical properties; fate and behaviour data, and health and environmental effects. Furthermore, information on natural nanomaterials, incidental nanomaterial by-products, and nanomaterials in research and development would also be informative.

Companies or parties who manufacture, import, process, or use nanomaterials will be asked to submit available information on those substances. The type of information that could be sought under an information gathering initiative may be similar to the current data requirements for chemicals and polymers under the NSNR. Additional data specific to nanomaterials (e.g., agglomeration, surface functionalization) would be useful as well. The US EPA Concept Paper for the Nanoscale Materials Stewardship Program under TSCA (US EPA, 2007) lists properties specific to nanomaterials. The OECD Working Party on Manufactured Nanomaterials is also examining properties and endpoints required for safety testing of nanomaterials.

Information gathered could allow Environment Canada and Health Canada to conduct preliminary risk assessments, provide insight to the types of information needed to conduct adequate risk assessments of nanomaterials, and assist in guiding the direction of current research activities.

VOLUNTARY INFORMATION GATHERING PROGRAM

A voluntary information gathering program is intended to benefit from corporate responsibility by encouraging industry to submit data on a voluntary basis. A voluntary program is considered a more informal initiative which can foster collaboration with industry and other parties. Such a program would provide guidance to industry on the types of information and methods of submission while also ensuring protection of confidential business information. This type of information gathering initiative could help build a knowledge base on nanomaterials, encourage the development of test data, and inform on any necessary risk management.

The information collected from a voluntary program would allow regulatory authorities to identify Canadian clients and the types of nanomaterials in use in Canada.
Nanomaterials which may be of concern for human health or the environment could be identified as well as the types of data necessary to conduct an informed risk assessment. Further steps could be taken to encourage the development of test data, the use of risk management practices, and to continue to promote the responsible introduction of nanomaterials to the Canadian market.

MANDATORY INFORMATION GATHERING

Notices under Section 46 or 71 of CEPA 1999 could be issued to companies making it a requirement for them to provide the requested information if available. The notices issued are applicable to those persons (e.g., individuals, companies, institutions, etc.) who are described in the notice. Response to such notices is mandatory and persons to whom the notice applies, must make efforts to answer the questions by providing information to which they ought to have reasonable access. In accordance with Section 313 of CEPA 1999, responding companies may submit with their information a request that it be treated as confidential. (Environment Canada, 2007d).

Notices issued using either of these provisions under CEPA 1999 would provide a description of the nanomaterials under investigation as well as the information be submitted.

RESEARCH AND DEVELOPMENT CONSIDERATIONS

Based on current understanding of the nanotechnology market in Canada, it is believed that a substantive amount of industrial nanomaterials are currently in the research and development (R&D) stage. Although the current regulatory framework has provisions for R&D substances, the volume of material required to trigger notification is high relative to quantities employed in an R&D setting. As a consequence, very few, if any, R&D nanomaterials would be subject to notification under the NSNR at this time. Nevertheless, the outcomes of research in the areas of materials science and environment, health and safety (EHS) can be informative to the development of a responsible regulatory framework.

The scientific research community can play an important role in the early stages of developing a regulatory framework through participation in information gathering initiatives and linking to research efforts by the OECD and the federal government. Researchers may possess basic information on nanomaterials (e.g., physico-chemical properties) or laboratories may have the capacity to generate data which can inform risk assessment and risk management.
PATH FORWARD

Nanomaterials are predicted to become significant in future commercial markets and beneficial innovations to health and environmental applications are anticipated; however, the potential risks arising from the novel properties of nanomaterials need to be addressed in a scientifically responsible manner. The development of an effective regulatory framework for nanomaterials in Canada will make use of the outcomes of international efforts and collaboration with industry. Information gathering initiatives will be developed in conjunction with industry and the public through multi-stakeholder consultations. This will be the first substantive step toward enabling the appropriate risk assessment and risk management of nanomaterials.

This multi-stakeholder consultation intends to obtain feedback and opinions on:

- Environment Canada and Health Canada’s approach to the development of a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999*
- The most effective approach to gather information on nanomaterials quickly and efficiently to inform the development of a regulatory framework.

Future consultations may be held on other aspects of the Environment Canada and Health Canada’s approach to regulating nanomaterials in Canada in order to ensure that the needs of both industry and the public are met through an open and transparent process.

Stakeholders are invited to provide written comments on the proposed regulatory framework and the options for information gathering to the following address:

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Gatineau, QC  
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REFERENCES


APPENDIX A

The New Substances Program Advisory Note 2007-06 can also be found at http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml.

New Substances Program Advisory Note 2007-06

Requirements for nanomaterials under the *New Substances Notification Regulations (Chemicals and Polymers)*

This advisory note is to inform manufacturers and importers of nanomaterials and any other stakeholders of the requirements for the substances under the *New Substances Notification Regulations (Chemicals and Polymers)*.

Background

Under the provisions of the *Canadian Environmental Protection Act, 1999* (the Act), the *New Substances Notification Regulations (Chemicals and Polymers)* [the Regulations] ensures that any new substance (whether a chemical or polymer) undergoes a risk assessment of its potential effects on the environment and human health.

If you manufacture in or import into Canada a new substance, you may be required to notify information with respect to this substance pursuant to the Act and the Regulations. The Act requires that the prescribed information under the Regulations be submitted to the Minister of the Environment prior to exceeding specific regulatory triggers either through the manufacture or import of a new substance.

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new. Any chemical or polymer not listed on the DSL is considered to be new to Canada and is subject to the notification requirements under the Regulations. Substances listed on the DSL do not require notification in advance of manufacture in or import into Canada.

The Act and the Regulations apply to new nanomaterials just as any other substance, whether a chemical or a polymer.

What is considered a nanomaterial?

Although there is no internationally recognized definition of this type of substance, nanomaterials can be described generally as substances having one or more dimensions in a nanoscale range, typically between 1-100 nanometers.

Canada is collaborating with international partners through the International Organization for Standardization (ISO) to develop standard terminology and a formal nomenclature system for nanomaterials.

What are the requirements under the Regulations for nanomaterials which are manufactured or imported?

Nanomaterials which are manufactured in or imported into Canada are subject to the same regulatory requirements as chemicals and polymers, and notifiers must submit a New Substances Notification
package prior to the manufacture in or import into Canada of the new substance (refer to Guidelines for the Notification and testing of New Substances: Chemicals and Polymers, Version 2005).

Although not required, Environment Canada and Health Canada recommend notifiers request a Pre-notification Consultation (PNC) during the planning or preparation of a notification. For example, a notifier can request a PNC to assist with determining whether the substance is notifiable, as well as to clarify notification procedures or information requirements, and to determine the acceptability of waiver requests and/or test protocols.

What nanomaterials are subject to the Regulations?

Nanomaterials which are manufactured in or imported into Canada that are not listed on the DSL are considered new. The nanoscale form of a substance on the DSL is considered a "new" substance if it has unique structures or molecular arrangements. New nanomaterials are subject to notification under the Regulations. For example, the nanomaterial fullerene (CAS No. 99685-96-8) is not listed on the DSL and is considered a "new" substance under the Regulations.

What nanomaterials are not subject to the Regulations?

Substances listed on the DSL whose nanoscale forms do not have unique structures or molecular arrangements are considered existing. Existing nanomaterials are not subject to the Regulations and do not require notification. For example, titanium dioxide (CAS No. 13463-67-7) is listed on the DSL and since its nanoscale form does not have unique structures or molecular arrangements, it is not subject to the Regulations.

In addition, incidentally produced or naturally occurring nanomaterials are not subject to notification.

Contact Information

New Substances Notification Information Line
Telephone:
1-800-567-1999 (toll-free in Canada)
1-819-953-7156 (outside Canada)
Facsimile: 1-819-953-7155
E-mail: nsn-infoline@ec.gc.ca

For additional information or documentation regarding the Regulations, please visit the New Substances Web site at www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

Original signed by

Bernard Madé
Director
New Substances Division
Environment Canada

Signed on June, 2007

1 Exceptions include those substances listed on the DSL and identified with a) an "S" flag that are proposed for manufacture or import and used for a significant new activity as defined in the Significant
New Activity Notice published for that substance, and b) a "P" flag and where the polymer substance proposed for manufacture or import is in a form that no longer meets the Reduced Regulatory Requirement polymer criteria.

2 Note: certain nanomaterials fall outside the typical nanoscale range. For example, fullerenes (bucky balls) have all three dimensions smaller than 1 nanometer, while quantum dots may have all three dimensions greater than 100 nanometers.

3 Manufactured nanomaterials are purposefully made, in contrast to incidentally produced or naturally-occurring nanoscale materials. They may be manufactured through chemical and/or physical processes to create materials with different or enhanced properties and/or structures compared to the macroscale material.
APPENDIX B

OECD Working Party on Manufactured Nanomaterials

The OECD Working Party on Manufactured Nanomaterials was formed in 2006 under the auspices of the Joint Chemicals Committee and includes representatives from governments, industry, and non-governmental organizations. The mandate of the Working Party is to coordinate international efforts on human health and environmental safety aspects of nanomaterials. Canada has been an active participant since the inception of the Working Party, playing a key role in the development of the Terms of Reference and the current Programme of Work (2006-2008).

The Working Party has identified six specific projects on various environmental, health and safety (EHS) aspects of nanomaterials and has established Steering Groups with country leads to address each project.

1. Development of an OECD database on EHS research (Australia)
2. EHS research strategies on manufactured nanomaterials (Germany)
3. Safety testing of a representative set of manufactured nanomaterials (United States, European Commission)
4. Manufactured nanomaterials and test guidelines (United States, European Commission)
5. Co-operation on voluntary schemes and regulatory programmes (Canada)
6. Co-operation on risk assessment (United Kingdom)

The Canadian Head of Delegation to the Working Party resides in the New Substances Division of Environment Canada and is also responsible for chairing Steering Group 5. Steering Group 5 aims to provide recommendations on effective approaches for information gathering initiatives and regulatory frameworks. As the chair of Steering Group 5, Canada is afforded a unique opportunity to inform the development of a domestic regulatory framework by drawing on the experiences of other countries which have or plan to implement various information gathering schemes.

ISO Technical Committee 229

Technical Committee 229 (TC 229) of ISO was formed in 2005 to address standardization in the field of nanotechnologies. The Canadian federal government is increasing its involvement in the activities of TC 229 through representatives from the federal Science & Technology community.

Within TC 229, three working groups (WGs) are convened by different countries to address specific subject matters.

- WG1: Terminology and Nomenclature (Canada)
- WG2: Measurement and Characterization (Japan)
- WG3: Health, Safety and Environment (United States)
Standard terminology and a standard nomenclature system are essential for the development of an effective regulatory framework. Precise identification of nanomaterials is needed in order to determine the appropriate regulatory track and ensure any appropriate risk management.
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