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National Consultation and Analysis on Nanomaterials and Their Implications for Human Health and the Environment

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Executive Summary

On January 27-28, 2016, *The National Consultation on Nanomaterials and Their Implications for Human Health and the Environment* was convened by Pollution Probe and the Trottier Institute for Sustainability in Engineering and Design (TISED) at McGill University in Montreal, Quebec. The workshop brought together representatives from industry, academia, government, and civil society. It was designed to engage key stakeholders in high-level knowledge-sharing and the identification of priority issues to advance the safe and responsible development and use of nanomaterials in Canada and internationally.

This report presents highlights from the workshop presentations and discussions, and analyses workshop outputs in terms of *advances* in four areas: science and knowledge, policy and regulation, public awareness and education, and stakeholder engagement. The analysis also identifies *gaps* that need to be addressed in each of these areas.

Based on the views expressed by workshop participants, ten priority areas were identified by Pollution Probe where further work could be undertaken to advance understanding and effective management of nanomaterials. The priorities are intended to stimulate broader discussion and agreement on actions to be taken by governments, industry and civil society stakeholders engaged in nanomaterials research and regulation.

The priorities that emerged from the workshop are as follows:

1. Develop a coordinated, Canada-wide nanomaterials research program.
2. Facilitate the effective use of existing data.
3. Develop a comprehensive, Canada-wide inventory of existing engineered nanomaterials and products containing nanomaterials already on the market.
4. Support the development of common terminology, definitions, nomenclature and classification of nanomaterials within the international community.
5. Enhance research on risk assessment.
6. Develop tools for quantifying and assessing risks and benefits of nanomaterials, using a multi-criteria evaluation approach, with the goal of determining whether specific uses of nanotechnology result in net social benefits.
7. Facilitate interdisciplinary collaboration and learning from international efforts in the areas of research, risk assessment and management as well as policy development on nanomaterials.
8. Develop a public engagement strategy on nanomaterials.
9. Study and implement safe nanomaterials routes and implement safer-by-design nanoproduct concepts.
10. Conduct a study on the potential of increased costs of nanomaterials-enabled products to assess their accessibility by low-income and vulnerable people.

The *National Consultation on Nanomaterials and Their Implications for Human Health and the Environment* was a joint initiative of Pollution Probe, the Trottier Institute for Sustainability in Engineering and Design (TISED), and the Brace Centre for Water Resources Management.

Pollution Probe is a Canadian charitable environmental organization (established in 1969) that is a leading agent of change at the intersection of communities, health and environment. Its approach is to define environmental problems through research, to promote understanding through education and to press for practical solutions through advocacy. Pollution Probe seeks to improve the health and well-being of Canadians by advancing policy that achieves positive, tangible environmental change.

Trottier Institute for Sustainability in Engineering and Design (TISED) within the Faculty of Engineering at McGill University is a think tank with a mission to produce innovative engineering and design solutions and intellectual capacity that enables the protection and nurture of Earth and its' inhabitants to meet the needs of current and future generations.

The Brace Centre for Water Resources Management is a multidisciplinary research and training centre of McGill University. The Centre brings together staff from several McGill faculties, to undertake research, teaching, specialized training, and policy and strategic studies in water resources management, both in Canada and internationally.

Acknowledgements

Pollution Probe, TISED and The Brace Centre for Water Resources Management thank the members of the Advisory Committee who volunteered to help define the direction and scope of the workshop, provide advice on scoping issues, identify potential speakers, and guide background research and the preparation of this report. Advisory Committee members included: Andrew Beck, Health Canada; Nicole Davidson, Environment Canada; Bruce Dudley, Delphi Group; Dr. Marie D'Iorio, National Research Council Canada; Brad Fisher, Environment Canada; Dr. Subhasis Ghoshal, TISED - McGill University; Brian Haydon, Canadian Standards Association; Myriam Hill, Health Canada; Ken Ogilvie, Independent Consultant; Lauren Penney, TISED - McGill University; Dr. Yasir Sultan, Environment Canada; Lorraine Tétreault, Health Canada; Dr. Nathalie Tufenkji, McGill University; Dr. Louise Vandelac, University of Quebec at Montreal (UQAM); Bob Oliver, Pollution Probe; Husam Mansour, Pollution Probe; Noemie De Vuyst, Pollution Probe; and Mariana Eret, Pollution Probe. Their perspectives and expertise were critical to the success of the workshop.

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Health Canada is thanked for providing financial assistance to analyze the workshop results and prepare this report on the findings.

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1.0 Introduction

Nanotechnology is a rapidly growing field in Canada and worldwide, focusing on the creation of materials through the manipulation of matter on the nanometer level. Engineered nanomaterials exhibit novel properties and behavioural phenomena that make them useful for diverse applications in industry, medicine, food and consumer products. While nanotechnology can offer benefits to society, there are many unknowns and concerns about the potential negative impacts of nanoparticles. Significant gaps in scientific knowledge underscore the lack of understanding as to how nanoparticles affect human health and the environment. Nanomaterials challenge Canada's *Chemicals Management Plan* (CMP), government's current chemical regulatory framework to manage these materials. Recognizing these challenges, Pollution Probe and the Trottier Institute for Sustainability in Engineering and Design (TISED) at McGill University held a multi-stakeholder workshop in January 2016 on engineered nanomaterials and their implications for human and environmental health. The overall goal was to facilitate capacity-building among key stakeholders, and to support the creation of an ongoing platform for multi-stakeholder and public engagement on issues of nanomaterials and public health. Through the workshop process, key priorities for action to advance the safe and responsible development and use of nanomaterials in Canada and internationally emerged.

Workshop and Report Objectives

Prior to the workshop, Pollution Probe and TISED convened an advisory group to provide guidance in setting objectives for the consultation. Three objectives were set:

- Engage experts and stakeholders in high-level knowledge-sharing and dialogue that educates and builds the capacity of participants to understand and engage in human health issues relating to engineered nanomaterials;
- Identify and characterize an initial list of priority issues that should be addressed; and
- Catalyze critical movement towards next steps to address the identified priorities.

Workshop Design and Process

On Day 1, the presentations and discussions were focused on knowledge-sharing and capacity-building among stakeholders on the subject of engineered nanomaterials in the context of human health and the environment. Day 2 was focused on identifying and prioritizing policy needs related to safe and responsible development of engineered nanomaterials.

More specifically, workshop sessions explored the following questions and issues:

- The uses and benefits of engineered nanomaterials;
- The impacts of engineered nanomaterials on human and environmental health;
- The state of science and knowledge gaps;
- The state of public knowledge and awareness on engineered nanomaterials;
- The application of the Canadian Chemicals Management Plan (CMP) to engineered nanomaterials;
- International experiences with the assessment and management of engineered nanomaterials; and
- Needs identification and prioritization.

Workshop participants represented diverse sectors including industry, academia, civil society and government from Canada, the US and the EU.

Section 2.0 of this report presents highlights of the presentations and breakout group discussions. The full presentation decks are available at http://www.pollutionprobe.org/nanomaterialsworkshop/.

Section 3.0 analyses the results of the workshop, and Section 4.0 identifies key themes and priorities for action.

2.0 Nanomaterials Workshop Presentations and Discussion Highlights

This section provides a brief summary of each speaker's presentation with the aim of providing a range of perspectives on the state of knowledge and regulation of engineered nanomaterials, including speakers' views on key gaps and priorities. The workshop agenda and speaker biographies are included in Appendix A and Appendix B.

Plenary 1-1: Nanomaterials in Our Daily Lives: Understanding Their Uses and Benefits

Dr. Mark Wiesner
Duke University, Professor of Civil & Environmental Engineering; Director, Center for Environmental Implications of Nanotechnology

Dr. Wiesner discussed the opportunities and challenges presented by engineered nanotechnology in the environmental services sector. Some proposed applications of nanomaterials are not likely to be cost effective, for example the removal of arsenic from water using nano-iron. Other proposed uses are in early development and have yet to be evaluated for feasibility and effectiveness, including the use of nano-labelled materials to enable waste sorting and recycling, and the design of electrically-conductive membranes to prevent fouling. Dr. Wiesner argued that the potential risks of engineered nanomaterials should be assessed against potential benefits, and that risks and benefits of nanomaterials should also be compared to those of alternative technologies.

Dr. Wiesner observed that our perception and understanding of the benefits, risks and uncertainties associated with new technologies evolves over time. When technologies are first introduced, there is a tendency to overestimate both risks and benefits. This changing perception means new technologies bring high levels of uncertainty, preventing investors from bringing innovations to market. Thus, Dr. Wiesner argued that research on risk is important not just to protect public and environmental health, but to ensure beneficial nanotechnologies can be efficiently brought to market.

To date, research suggests that the risks posed by the use of the engineered nanomaterials most commonly used in commerce, such as TiO_2 and silver nanoparticles, are relatively low compared with known contaminants such as heavy metals and chlorinated aromatic organic compounds. In addition, Dr. Wiesner said that studies to date showing that nanomaterials had negative health or environmental effects tended to fall into at least one of four categories: 1) the studies used unrealistically high doses, 2) the studies used cell cultures, rather than whole organisms; 3) the materials studied were already

known to be toxic; and 4) the studies involved pristine nanomaterials, rather than aged nanomaterials or materials embedded in other substances, factors that tend to mitigate toxicity and/or exposure. With regard to ecosystem level impacts, some subtle effects have been observed on nutrient cycling, and trophic transfer of materials through food webs has been observed. However, the implications of these effects are not yet well understood.

Dr. Wiesner stressed the importance of putting these findings in the context of what human populations are likely to be exposed to, noting that exposure to naturally occurring nanomaterials is much higher than to engineered nanomaterials. He concluded that a number of the applications proposed in the environmental services sector are associated with high capital costs, and that in general the use of nanomaterials may yield incremental, rather than game-changing, benefits.

Dr. John Dutcher

University of Guelph, Professor, Department of Physics

Dr. Dutcher discussed opportunities and challenges of nanotechnology in food, pointing out that many foods contain naturally occurring nanomaterials, such as the casein micelles in milk. He highlighted potential benefits of the use of engineered nanomaterials in the food industry; for example, nanomaterials can enable "smart packaging" and can be used to implement DNA barcoding to trace the origin of foods.

Despite this positive effect of nanotechnology in foods, many questions and potential challenges remain. For example, the stability of nanostructures and complex formulations is a concern. In terms of safety, the possibility of unexpected health consequences due to novel technology must be considered, such as whether engineered nanomaterials will be eliminated from the body or accumulate over time.

Consumer acceptance is another barrier to the use of engineered nanotechnology in food. Dr. Dutcher called for public education on its advantages and risks. He highlighted the National Nanotechnology Initiative, a US program which familiarizes school-age children with information about nanotechnology so that they are able to make informed decisions.

Cost is also a barrier to the integration of nanotechnology into the food industry. Modifying nanoparticles to achieve new functionality adds steps in the manufacturing process, increasing costs. A key concern is whether new food nanotechnologies will be inexpensive enough to be adopted by the vulnerable populations for whom they are designed.

To conclude, Dr. Dutcher laid out a proposed path forward for nanotechnology in food. First, the risks and benefits of nanomaterials must be identified and quantified. In addition, government policies and regulations should be made on a scientific basis. Consumers should also be educated so they can make informed decisions. Finally, Dr. Dutcher emphasized that safe, natural nanotechnology routes should be pursued where possible, using nanoparticles and nanostructures found in nature to achieve desired functionality in foods.

Dr. Lajos P. Balogh

AA Nanomedicine & Nanotechnology, Chief Scientific Advisor and Principal

Dr. Balogh gave an overview of the emerging field of nanomedicine. He noted that nanoscale particles are an integral part of the world and are not inherently dangerous – instead, risks are associated with a

lack of knowledge. Nanomedicine aims to utilize nanoscience and nanotechnology in life sciences by creating more effective devices, drugs, pharmaceuticals and other medical tools to improve health. Nanomedicines can offer greater multi-functionality and complexity than conventional medicines. For example, they are able to better target disease sites and can reduce systemic toxicity considerably. Research also shows that nanomaterials can be used to treat metastasis, a condition with a high mortality rate. Other potential uses include the stimulation of bone formation through bioactive nanoparticles, the regeneration of nerves and the detection of lung cancer biomarkers in a patient's breath, and others. Dr. Balogh stated that, despite studies indicating significant benefits, the commercialization of nanomedicine has been slow, and business successes to date have been scarce.

Dr. Elizabeth Nielsen

Consumers Council of Canada, CSA Consumer Representative

Dr. Nielsen discussed the range of engineered nanomaterials in consumer products, their benefits, and the concerns and consumer trust issues raised by their use. In the past 10 years, the use of nanomaterials in consumer products has rapidly increased; an inventory prepared by the Woodrow Wilson International Center for Scholars listed 54 products in 2005, but more than 1800 products in 2014. The use of nanomaterials has led to important benefits, including reducing side effects from drugs, enabling implantable sensing devices that give real-time measurements of bodily functions, rebuilding nerves and tissues, improving imaging for diagnostics, and enhancing anti-bacterial agents.

Despite these benefits, concerns about the use of engineered nanomaterials in consumer products remain. A key concern is a lack of knowledge on nanotechnology and its potential impacts on public health and the environment. In addition, the slow development of measurement tools and procedures means that assessing nanomaterial effects is challenging. From a consumer perspective, the absence of labelling prevents the public from making informed purchasing decisions. Dr. Nielsen stated that, in order for nanotechnology to be accepted by consumers, scientists and researchers must become more informed about consumers' concerns and needs. In terms of regulation, many consumer products go to market without pre-market evaluation, and the rapid pace of commercialization means that government bodies cannot ensure effective legal oversight.

The use of engineered nanomaterials in consumer products also raises important ethical questions. In terms of transparency, consumers, manufacturers, and other stakeholders are left with questions about who has the authority to introduce new substances to the market. On privacy, some are concerned about the potential to track individuals with sensors enabled by nanomaterials. How these questions are answered will affect public trust, influencing the future of nanotechnology innovation. Dr. Nielson stated that there is a medium to high probability that the issues of engineered nanomaterials in consumer goods will be perceived by consumers as a "public crisis". Dr. Nielsen concluded that an important challenge is how to realize the societal benefits of nanotechnology while minimizing adverse impacts.

Plenary 1-2: Impacts of Nanomaterials and Their Implications for Human and Environmental Health

Dr. Alistair Boxall
University of York, United Kingdom, Professor of Environmental Science

Dr. Boxall presented research on human exposure to nanomaterials in the environment, in particular through drinking water. His study, which focused on the situation in the UK, determined the likely exposure of consumers to nanomaterials in the environment arising from consumer products, paints and coatings and fuel additives. The study found that for the vast majority of products examined, drinking water exposure was insignificant compared to exposure from the day-to-day use of the products.

Dr. Boxall also discussed future research on exposure modelling of nanoparticles and other chemicals. At present, his team is developing an exposure model for the city of York in the UK, addressing both human and environmental exposure to nanomaterials. By mapping climatic variables and how individuals interact with the natural environment of the city, the research aims to estimate citizens' exposure to pollution throughout their lifetimes. This requires modelling at high temporal and spatial resolutions. To date, research suggests that for most products containing nanomaterials, environmental exposure is not the most important route. However, as the uses of nanotechnology become more diverse, this may not hold true. Currently, lack of usage information and emissions data limit researchers' ability to accurately estimate exposure.

Dr. Chris Metcalfe
Trent University, Professor and Chair, Environmental and Resource Studies; Director, Institute for Watershed Science

Dr. Metcalfe addressed the fate and effects of engineered nanomaterials in the environment, and discussed major gaps in research to date. He focused primarily on studies examining the fate and transformation of metal-based nanoparticles, noting that most of the toxicity of metal nanoparticles in laboratory experiments can be attributed to the amounts of dissolved metal released into solution. Dr. Metcalfe raised the issue of whether studies using "pristine" materials are environmentally relevant, considering that nanoproducts contain nanomaterials in matrixes that release them over time, so they are often subject to aging or weathering. He noted that investigations with "aged" nanomaterials are rare. Such studies, however, are key to understanding environmentally relevant exposure. Dr. Metcalfe concluded that as the science develops, it will become possible to assess the concentration of nanoparticles in various environmental matrixes, as well as the hazards to the environment from nanoparticles released from nanoproducts. This will enable us to make informed decisions about the potential environmental impacts of the development of nanotechnologies.

Session 1-3A: Understanding the State of Science and Research Gaps

Dr. Frank von der Kammer
University of Vienna, Senior Scientist and Lecturer, Department for Environmental Geosciences

Dr. Frank von der Kammer focused on the challenges of exposure assessment of nanomaterials in real world conditions. In order to assess the exposure of organisms to engineered nanomaterials, he stated

that there is a need better understand the fate and behaviour of nanomaterials in the environment, their uptake by biota, and their presence and release from consumer products. Detection, quantification, and characterization of engineered nanomaterials in environmental media is key to understanding the processes through which exposure might occur.

Dr. von der Kammer highlighted a number of advances in methodologies and tools for detecting, quantifying and characterizing nanomaterials. In particular, progress has been made towards the development of validated methods to classify raw industrial products containing engineered nanomaterials, as well as tools to quantify the release of nanomaterials from these products. In addition, a broad knowledge base has been developed on the natural and anthropogenic sources of airborne nanoparticles, and networks have been established to monitor the presence of nanoparticles in the air. There are also a growing number of methods to sample and characterize nanoparticles in groundwater, soil, and sediment. However, Dr. von der Kammer stated that further improvements are needed to enable more accurate exposure assessment.

Dr. Greg Goss

University of Alberta, Professor of Biological Sciences; Director, National Institute for Nanotechnology

Dr. Goss emphasized that many important advances in the science and regulation of nanotechnology have been made, but that many gaps still remain. In science, recent work has led to an improved understanding of the physics of nanomaterials and their potential impacts on biological processes. Methods for assessing toxicity have also improved; more researchers are now working with "environmentally realistic" concentrations, although there is still debate about how this type of concentration should be defined. In terms of regulation, Dr. Goss stated that harmonization of regulatory efforts is now well underway, including the development of reports and guidance documents by the Organization for Economic Development and Cooperation (OECD).

Despite these advances, the existence of many knowledge gaps makes it difficult to assess the risks posed by nanotechnology. In addition, predicting future trends is challenging because the evolution of nanotechnology and its uses will change uptake and release scenarios. As a result, current knowledge offers little predictive power for future environmental and human health effects.

Other problematic gaps include a lack of a formalized nomenclature system, which creates issues in the assessment and registration of materials. Additionally, the absence of a coordinated research system for nanomaterials in Canada means there is often a lack of communication across disciplines and a fragmented approach to interacting with international researchers.

Session 1-3B: Exploring the Technological Applications of Nanomaterials

Dr. Darren Anderson

Vive Crop Protection, Chief Communications Officer & Vice President Regulatory

Dr. Anderson highlighted the potential uses of nanotechnology in agricultural pesticides, stating that nanotechnology-based delivery technologies can direct pesticide active ingredients to precisely where they are needed. He described this process as analogous to drug delivery; in heart medications, the delivery system is carefully designed to ensure that the drug reaches the heart but has minimal side

effects. Well-designed delivery systems can have similar properties for applications including agriculture, environmental remediation, consumer products, and others. Currently, a significant proportion of applied pesticides are released into the environment, affecting non-target organisms such as pollinators– an outcome that the use of nanotechnology in pesticide application could reduce.

Dr. Anderson also pointed out that the terms nanotechnology and nanomaterials cover an "incredibly broad" range of substances, presenting significant regulatory challenges. This means it is likely not possible to create a general risk or benefit assessment framework for nanomaterials. Instead, assessments must be specific to the case of interest. Questions to ask during assessment include what the nanoscale component is designed to do, what benefits it provides, and whether nanoscale form presents greater risks than the conventional form.

In addition, Dr. Anderson stated that nanoscale particles may have properties that are fundamentally different to those of non-nanoscale forms of the same material. This means that it is not possible to extrapolate properties of the nanoscale form from the known properties of a material. Dr. Anderson suggested that one way to assess potential risks would be undertake a limited subset of comparative studies on nanoscale and non-nanoscale forms of materials. He stated that to date, Vive Crop Protection has done over 45 such studies, and that these show no difference in hazard between the nanoscale and non-nanoscale forms.

Finally, Dr. Anderson argued that it is critical to encourage the development and adoption of new technologies. Currently, the cost of bringing a new product to market typically exceeds $300 million, creating significant barriers to the introduction of new products. Dr. Anderson said that for new technologies with the potential to dramatically improve pesticide targeting, it is critical to make any additional required testing manageable by small companies. If regulatory requirements are too high, it is likely that new development will be stifled. He argued that if there is regulatory support for a practical level of requirements, innovation could be unleashed, similar to what has happened with bio-pesticides in the agriculture industry.

Dr. Greg Lowry

Carnegie Mellon University, Professor of Civil and Environmental Engineering

Dr. Lowry addressed the need to quantify both risks and benefits of nanomaterials, arguing that tools should be developed in order to determine whether nano-enabled products lead to net societal benefits. In the past, new products with known benefits, for example DDT and CFCs, have been released into the environment without rigorous risk assessment and have resulted in damage to human and environmental health. Dr. Lowry argued that a proactive approach to risk assessment should therefore be applied to nanotechnology. He proposed that, during risk assessment, questions should be re-framed from whether a nanoparticle will cause harm to whether the benefits will outweigh the negative impacts. Key questions would include whether nanomaterial substitutions for existing chemicals improve products, whether substitutions result in overall lower environmental impacts, and how to best quantify the net lifecycle impacts of nano-enabled products. He concluded that better approaches are needed to quantify the benefits of engineered nanomaterials, including the development of a framework and tools to determine the design of nano-enabled products that lead to net social benefits.

Dr. Michael Fleischauer
National Research Council Canada, National Institute for Nanotechnology, Associate Research Officer, Program Coordinator – Energy; University of Alberta, Department of Physics, Adjunct Professor

Dr. Fleischauer stressed the importance of understanding how nanotechnology will be applied, as different types of nanomaterial can have very different properties. For example, the terms nanocrystalline, nanostructured, and nanosized can all mean different things, so distinguishing between different forms of nanotechnology is important in regulation.

In terms of risk assessment, Dr. Fleischauer stated that it is important to understand the entire supply chain of a nano-enabled product and the associated value proposition. He also argued that while nanotechnology can provide benefits, it should not automatically be assumed to be a better option than conventional products. In some cases, products containing nanotechnology can result in worse outcomes than conventional products.

He also stated that industry and government are generally willing to talk about problems they want solved, although he also said researchers do not always listen to findings and advice.

Session 1-3C: Applying the Canadian Chemicals Management Framework to Nanomaterials

Ms. Myriam Hill
Health Canada, Section Head, Nanotechnology

Myriam Hill discussed the regulation of nanomaterials under existing chemicals management frameworks. Most jurisdictions and OECD members agree that existing frameworks offer a firm foundation for the regulation of nanomaterials, but adaptations to current regulations may be needed in some cases.

In Canada, engineered nanomaterials are regulated under a series of acts, depending on their use; for example, nanomaterials in consumer products fall under the Canada Consumer Products Safety Act, and those in industrial chemicals are regulated under the Canadian Environmental Protection Act (CEPA). While CEPA does not specifically define nanomaterials, it defines chemical substances broadly enough to be applied to nanomaterials. Under CEPA, any materials not listed on the Domestic Substances List (DSL), including nanomaterials, are considered new substances and must undergo an assessment before entering the Canadian market. However, new substances imported or manufactured in volumes below the trigger quantity are not subject to notification under the framework quantity (the trigger quantity is 100 or 1000 kg/year, depending on the Schedule being notified and whether the substance in question is on the Non-Domestic Substances Lists (NDSL)). There are also no notification requirements for substances imported as part of manufactured articles under the New Substances Notification Regulations (Chemicals & Polymers) (NSNR (C&P)).

Ms. Hill also addressed Health Canada's approach to risk assessment with respect to nanomaterials. Health Canada uses a lifecycle perspective for risk assessment; however, while risk is generally a function of both hazard and exposure, in the absence of adequate hazard information control measures are used to minimise exposure. If a nanomaterial is determined to pose a significant risk, proposed management actions could include imposing conditions on use or prohibiting the substance.

For nanomaterials already on the market in Canada, a draft approach similar to the chemicals management plan has been developed. This approach would involve the validation of current understanding of the status of nanomaterials on the domestic inventory, the development of a prioritization process for the assessment of these nanomaterials, and examining priority nanomaterials for their potential effects on human and environmental health.

Mr. Troy Winters

Canadian Union of Public Employees (CUPE), Senior Health & Safety Officer; Vice Chair, CSA Technical Committee OHS – Nanotechnology

Troy Winters addressed two key areas: how to quantify and control risks posed by nanotechnology, and the nanotechnology standards that exist in Canada. With respect to quantifying risk, he outlined key questions to ask, including how materials enter the body, how toxicity is assessed, how exposure is measured, and how it should be controlled. From a worker perspective, he stated that the most important question was simply whether engineered nanomaterials exist in the workplace. Employers are often unaware that they are using nanomaterials, as the Chemical Abstracts Service (CAS) registry number does not distinguish between nanomaterials and conventional materials. He also noted that the Occupational Safety and Health Act does not require companies to take any specific measures when using nanomaterials. He went on to present options for controlling risk in the workplace, including the elimination or substitution of nanomaterials from the workplace, applying engineering techniques, and the use of personal protective measures.

Mr. Winters also gave an overview of standards for nanotechnology that are in use in Canada. Canada is a member of the ISO and IEC, major international standards development organizations that have been working on nanomaterials for more than 10 years. These nanotechnology standards are available for adoption in Canada. In addition, several Canadian standards are in place (e.g., CSA Z12885-12, CAN/CSA-ISO/TR 13121:13, CAN CSA-Z13329 15, CAN/CSA-Z12901-2:15) that address issues such as risk management and evaluation, reduction of hazards and exposure, and unknown risk from new nanomaterials. Winters stated, however, that standards are not implemented as well as they should be. There is sometimes a reluctance to adopt the standards, even though they are a way to harmonize approaches internationally. He also noted that smaller companies are at a disadvantage as they lack the resources to participate in standards development.

Mr. Winters highlighted the need to educate the public about nanomaterials policy and regulations. He noted that all stakeholders should be able to participate in the regulatory process, with government as the arbiter among differing views. The Chemicals Management Plan allows for this to happen in an open and transparent process, and Mr. Winters emphasized that Canadians should be made aware of this. He said that government has lost visibility and trust as insufficient attention has been given to broader education and awareness building. He stated that greater public trust can be facilitated by increased international cooperation and consensus on the benefits and risks of nanotechnology and nanomaterials. In addition, he said that while nanotechnology has faults, he looks forward to the progress to be gained through the use of new technologies. He concluded that there is a need to move away from sensationalizing issues and instead to promote more robust public dialogue, as the term “nanotechnology” tends to have negative connotations and can lead to misconceptions.

Mr. Beta Montemayor

Canadian Cosmetic Toiletry and Fragrance Association, Director, Environmental Science and Regulation

Beta Montemayor reflected on what he had heard during the morning session of the workshop. He noted four key themes: building trust and knowledge, data sharing and meeting data needs, learning from the past, and balancing the public narrative by including the benefits of engineered nanomaterials. He observed that the public may feel that there is no nanomaterials regulatory system in place, but we do have a robust chemicals management system that includes nanomaterials. The system is science-based and risk-based, with exposure determining how risk is dealt with. He concluded that there is a need to do a better job of educating the public on the regulatory system that is in place, as well as a need to bring all stakeholders together on this issue.

Plenary 1-4: Group Discussion

During this plenary session, speakers and participants convened to identify key themes from the first day of the workshop. These included a need for strengthened public awareness of nanotechnology and how it is regulated, and a need for increased data sharing and international collaboration among researchers.

Several participants discussed the possibility of labelling as a solution to the public awareness gap; however, there was disagreement on this issue, as some participants asserted that labelling of nano-enabled products could create a negative image and inhibit beneficial uses. Others suggested that this could be avoided if labels included information on the benefits conferred by nanotechnology. Furthermore, regulators clarified that the use of labelling as a risk management tool must meet certain regulatory requirements and cannot be used in the absence of an identified risk to human health.

On scientific research, participants stated that considerable data have already been generated and that validating existing data sets, which vary in quality, is as important as generating new data. In addition, participants called for measures to encourage private companies to share their data on risk assessment and efficacy testing.

In terms of knowledge gaps, participants pointed to toxicology as an area where more research on engineered nanomaterials is needed. They also said there was a need for more co-ordinated interdisciplinary research efforts.

Finally, participants called for safer-by-design concepts to be applied to new products.

Plenary 2-1: International Experiences and/or Approaches to Assessment and Management of Nanomaterials

Mr. Jim Alwood
US Environmental Protection Agency, Office of Pollution Prevention and Toxics, Program Manager

Mr. Alwood outlined the key steps taken by the US Environmental Protection Agency (EPA) to regulate nanomaterials. In the US, engineered nanomaterials are regulated under the existing framework established by the Toxic Substances Control Act (TSCA), which is typically used to regulate industrial chemical substances. The TSCA provides the EPA with the authority to gather information, require testing, screen unreasonable risks and coordinate with other regulatory agencies on issues relating to chemical substances. It classifies chemicals into two categories: “existing” chemicals are defined as those listed on

the TSCA Inventory, while “new” chemicals are those that are not listed. This structure presents some challenges for the regulation of engineered nanomaterials as the TSCA inventory list defines chemical substances by molecular identity, and not by particle size. The result is that the introduction of novel nanomaterials to the market may not require regulation under the TSCA.

To date, the EPA has received more than 170 new chemical notices for nanomaterials. While the EPA takes no action on 85%-90% of new chemicals, 100% of nanomaterials proposed for the market receive further review, including risk assessment. For conventional chemicals, risk assessment would typically establish an exposure limit, either based on test data or the best available analogue. However, for nanomaterials, better data on human and environmental exposure is needed for a more conclusive risk assessment. Most nanomaterials that have gone through the review process are now allowed in commerce under certain restrictions, including requirements to prevent human and environmental exposure and requirements to develop data. The review and regulation process can take 6 – 24 months per substance.

Currently, the EPA is working to collect data on nanomaterials that are already in commerce. In 2015, the EPA proposed an Information Gathering Rule to ensure that they have basic information on nanoscale materials on the market. This will improve their ability to assess risks posed by nanomaterials and to make appropriate risk management decisions.

The EPA also plans to implement several additional steps to enhance regulation. Firstly, work is needed on the classification of nanomaterials; there is a need to determine what parameters make nanoscale materials sufficiently similar to allow for “read-across”, as it is not possible to test every form of a nanomaterial. Such parameters need to be refined to aid the development of more precise subclasses. Additional scientific research and expert input were identified as key to further refinement of classification. Finally, the need to further develop terminology, definitions and nomenclature, especially within the international community, were suggested as areas for further action.

Dr. Mark Wiesner

Duke University, Professor of Civil & Environmental Engineering; Director, Center for Environmental Implications of Nanotechnology

Dr. Wiesner focused his remarks on issues related to the system of price information conveyed to the market for nano-enabled products. He commented on the externalities of costs and benefits that are not captured by markets unless regulations, legal frameworks and/or taxes are put in place. He observed that the quantities of naturally occurring nanomaterials in the environment are thousands of times greater than the volume of engineered materials in the environment, many of which are similar or identical to natural materials, raising the question of the best practices required to manage risk. He reiterated that the largest production quantities of engineered nanomaterials tend to fall into low-risk categories based on research performed to date. He pointed out difficulties in regulating nanomaterials as a class of materials, beginning with disagreements in the international community on how to define these materials, and that existing categorization schemes that are flawed. As an alternative approach for regulatory purposes, he proposed that new materials that might otherwise be candidates for regulation by categorized and regulated as nanomaterials, based on the functional properties of these materials (e.g., photocatalytic, mechanical strength, etc.) which would allow for "nano" and "non-nano" alternatives to be compared based on both possible risks and benefits.

Dr. Antonia Praetorius

University of Vienna, Postdoctoral Researcher, Department of Environmental Geosciences

Dr. Praetorius provided an overview of the state of regulations on engineered nanomaterials in the European Union. The European Commission has introduced a number of product-specific regulations relating to nanomaterials. These include an EU cosmetics regulation (1223/2009), an EU biocide regulation (528/2012), and an EU Food Labelling Regulation (1169/2011). The EU has also introduced a requirement to label nanomaterials in certain products. For example, cosmetics manufacturers are required to list titanium dioxide on labels as "titanium dioxide (nano)".

With respect to introducing a regulatory definition for nanomaterials, the Commission issued a recommendation on a definition in 2011. However, Dr. Praetorius identified a number of remaining questions facing the Commission's regulators, including whether the proposed definition can be effectively implemented, and how compliance with the regulations would be enforced.

Dr. Praetorius also provided a brief overview of the EU's REACH program (Registration, Evaluation, Authorisation and Restriction of Chemicals). Implemented in 2007, REACH applies to high volume industrial chemicals that are already in use but do not fall under any of the specific regulations. The Commission launched a comprehensive REACH Implementation Project on Nanomaterials (RIPoN) in 2009 to provide advice to industry on key aspects of the implementation of REACH with regard to nanomaterials. Dr. Praetorius noted that, after 2018, usage of chemical substances with volumes of one tonne per year or greater will have to be registered under REACH. According to Dr. Praetorius, the basic requirement can be summed up as: "no data, no market".

Mr. Brad Fisher

Environment and Climate Change Canada, Manager, Nanotechnology Section, Science and Technology Branch

Mr. Fisher presented an overview of Canada's international involvement in nanomaterials science, policy, and regulation. Canada continues to be very active in various international fora, including participation in ISO TC229, which addresses nomenclature, metrology, and measurement, and the International Union for Applied Chemistry (IUPAC), which addresses nomenclature for nanomaterials. During his presentation, Mr. Fisher focused most strongly on Canada's involvement in the OECD Working Party on Manufactured Materials (WPMN), and the major outcomes of the Canada-U.S. Regulatory Cooperation Council (RCC) Nanotechnology Initiative.

In 2013, the OECD published a recommendation stating that existing regulatory frameworks can be used for nanomaterials, with some nanomaterials-specific modifications. Canada, along with other member states, has endorsed this recommendation, and is in the process of implementing it into the domestic regulatory program.

Canada has also been a contributor to several important OECD WPMN initiatives, including a large-scale research program that focused on generating environment, health and safety data on nanomaterials in commerce. Canada is also contributing to adapting test guidelines developed for traditional chemicals to accommodate nanomaterials and is using this forum to share lessons learned and best practices in implementing regulatory approaches for nanomaterials.

Mr. Fisher also provided an overview of the major outcomes of the RCC Nanotechnology Initiative including the development of policy principles to guide the regulation of nanomaterials in both countries, the development of a categorization scheme to aid in regulatory decision making and the sharing of risk assessment and risk management approaches. He noted that Canada and the US regulatory systems have some differences, but cooperation under the RCC ensures consistent approaches and enhances information exchange.

Facilitated Breakout Session 2-2: Needs Identification and Prioritization

In this session, workshop participants discussed and debated a list of needs and priorities for Canada with respect to safe and responsible nanomaterials development.

Participants identified the need to develop a framework that would allow scientists, policy-makers, and industry to holistically quantify the benefits and risks of nanomaterials to ensure that decision-making is not driven entirely by risk mitigation. Such an approach would make it possible to determine when benefits quantifiably outweigh risks. In addition, participants identified a need to take an interdisciplinary approach to risk assessment, balancing the scientific approach to risk assessment with the public's perception of risk.

Many participants identified the need for more robust interaction and data sharing between academia, regulators and industry. This would help to ensure that nanomaterials research in the academic sector is driven by needs perceived by the industry as well as the broader market, allowing research funding to be allocated more efficiently.

Enhancing safer-by-design practices for nanomaterials was also identified as a priority area.

Another priority for action was building consumer and public trust in nanomaterials and their regulation. There was broad support for more community outreach and education on issues around nanomaterials. Participants identified a range of issues and questions that should be tackled in this regard, including the need for knowledge translation to bridge the gap in public understanding of nanotechnology. In addition, participants raised the question of who should be responsible for the dissemination of information to the Canadian population. It was pointed out that the Government of Canada has been active in communicating the latest information on nanotechnology to the general public and consumers via the Canada Gazette and the NanoPortal. However, participants felt that the reach of these information sources is limited. Participants highlighted an opportunity for non-profit organizations, educational institutions and other parties to take on a greater role for knowledge translation and communication.

Finally, participants highlighted the importance of transparent science, relevant and reliable data and clear, balanced communication for building public and consumer confidence and trust. It was also noted that the perception of reliability is influenced by whether data are generated through research funded by independent sources. Government funding for research on nanomaterials in government laboratories or in the university system was suggested as critical to producing reliable data and building public trust.

McGill Students Panel

Kerwin Wong, Laura Hernandez, and Ryan Maliska

Several McGill Chemical Engineering students who took notes and assisted facilitators with the workshop were asked to give their reactions to what they had heard during the two days. The students posed the question of how the workshop information could be packaged in ways that will help the public to understand issues relating to engineered nanomaterials. They observed that many speakers indicated that there is a need for education and dissemination of responsible information through the school system, as well as a need for more multi-stakeholder and multi-disciplinary discussions. They also raised the question of what message should be communicated to the public, who should prepare this information, and who should be responsible for communicating it. They stated that if the goal is to develop broad approval of nano-enabled products, then many disciplines, in addition to scientists, engineers and regulators, need to be engaged.

The students also suggested that there was a need to categorize nanomaterials in ways that are useful to scientists and regulators, but also to end consumers. They posed the question of what labels containing information on nanomaterials would mean to the public.

The issue of affordability was also raised, and whether nano-enabled products would be accessible to lower-income and vulnerable individuals, and to individuals in developing countries.

Overall, the students felt the consultation offered a very high-level view of issues related to nanotechnology, but that there was often too much focus on workshop participants' sector-specific needs. For future dialogues on nanotechnology, they also called for participation from sociologists, psychologists, civil society groups, and other sectors.

Plenary 2-3: Group Discussion – Policy Café

Participants in this session discussed approaches to risk assessment and data sharing. With regards to risk assessment, it was suggested that engineered nanomaterials must be assessed on a case-by-case basis, as different substances raise different sets of questions. Some suggested that the best form of risk assessment for these materials may be alternatives assessment, while others advocated for a lifecycle assessment approach. Participants also stated that risk-benefit analysis should be multi-objective, and not reduced to a single criterion, such as cost.

Data issues were another topic of discussion. Attendees agreed that there is a paucity of data exchange among stakeholders. Partnerships between academia and industry were suggested as an incentive to encourage industry to share data. In North America, most data are restricted by confidentiality agreements, which means making findings publicly available is challenging. In contrast, some European companies are providing datasets to academic projects and are working collaboratively to analyze them. Some participants, however, gave the view that US companies are unlikely to release all their data publicly, although they may share it selectively if that is to their advantage.

Workshop participants also suggested that governments should share their curated datasets with researchers. One participant responded that sharing data would have to be a coordinated effort, and that creating a single database for all stakeholders to use is unrealistic. In addition, it was said that researchers

will be unwilling to share unpublished data, so efforts should be focused on sharing published data. Participants also stated that a great deal of data has already been collected, but that efforts must be made to use this data more effectively.

Finally, participants identified the need to quantify both the benefits and risks of engineered nanomaterials. Several participants argued for the need to develop a multi-criteria evaluation system. However, this can be challenging as instruments specifically designed for assessing engineered nanomaterials do not exist, as manufacturers do not see a strong enough market to develop them.

3.0 Analysis of Results

This section draws upon the workshop presentations and discussions to assess both advances and gaps in four key areas:

- Science and knowledge
- Policy and regulation
- Public awareness and education
- Stakeholder engagement

The analysis in this section reflects the views presented during the workshop, and does not aim to offer a comprehensive overview of advances and gaps identified in other fora. Instead, it identifies common ideas and issues highlighted by workshop participants.

3.1 Science and Knowledge

Advances

Participants agreed that the use of engineered nanomaterials has the potential to offer benefits in many sectors, including medicine, environmental services such as water treatment, the food industry, and consumer goods. Nanomaterials have already contributed to improvements in current technologies, processes and methods, as reflected by the rapidly growing market for nanomaterials. It was noted, however, that many of the potential applications of nanotechnologies may yield incremental, rather than game-changing, benefits.

In general, participants suggested that recent research has led to significantly improved knowledge of engineered nanomaterials, their physical properties, and their potential impact on biological processes. In particular, methods for assessing toxicity and exposure routes have improved.

Several speakers also indicated that, unless engineered nanomaterials are produced from known toxic substances, they may have fewer negative human health impacts than once feared.

Gaps

Improved use and sharing of existing data was identified as an important area for additional work. Several participants called for renewed efforts to analyze, validate, and share existing data. Suggestions for encouraging data exchange among stakeholders included creating partnerships between industry and academia, as is done in Europe. In addition, participants stated that a lack of a coordinated research system in Canada results in a lack of communication and data sharing.

Participants also identified specific research gaps. One was the need for studies representing conditions more similar to those that would be found in the environment. To date, many studies have been conducted using pristine engineered nanomaterials in laboratory settings – this does not represent real-world conditions, as nanomaterials have a tendency to transform in the environment. As a result, existing data may not offer information on health and environmental impacts of the engineered nanomaterials already on the market. In terms of knowledge gaps, toxicology and ecosystem effects were identified as areas where further research was required. In the food sector, speakers identified knowledge gaps with respect to biological impacts of ingesting engineered nanomaterials.

The uncertainties created by these gaps pose challenges to risk assessment; a lack of data on potential hazards posed by nanomaterials means that assessment is largely based on exposure. In addition, current knowledge of nanomaterials and potential risks to the environment offers little predictive power for future impacts as more nano-enabled products are brought to market.

3.2 Policy and Regulation

Advances

Harmonization of nanomaterial regulatory efforts is now well underway, including the development of reports and guidance documents by the OECD. The European Commission has introduced a number of product-specific regulations for the EU relating to nanomaterials, and now requires labels to contain information on nanomaterials in certain products.

In 2015, the U.S. EPA proposed an Information Gathering Rule to ensure that basic information on nanoscale materials on the market is collected. For nanomaterials already on the market in Canada, a draft approach similar to the chemicals management plan has been developed. This approach involves the validation of current understanding of the status of nanomaterials on the domestic inventory, the development of a prioritization process for the assessment of these nanomaterials, and examining priority nanomaterials for their potential effects on human and environmental health.

Gaps

While the existing chemicals management framework in Canada covers nanomaterials, several participants noted that engineered nanomaterials present some challenges to the framework – especially with regards to CEPA's Domestic Substances List (DSL). Firstly, information requirements for new substances are tailored to chemicals and polymers and are not always appropriate for nanomaterials. In addition, there are no notification requirements for nanomaterials imported as part of manufactured articles, and nanomaterials imported or manufactured in volumes below the trigger quantity are not assessed. The current regulatory framework also means that many novel engineered nanomaterials go to market without assessment because they do not reach the assessment trigger threshold (100 or 1000kg/year).

More generally, the difficulty of categorizing nanomaterials is a key challenge to regulation. A number of approaches to classification were mentioned at the workshop, but each approach has benefits and drawbacks. There is a need to ensure that any categorization scheme enables beneficial substances to reach the market efficiently. Clarifying the criteria for the categorization of nanomaterials is a priority, as is working towards universal terminology and definitions. There is also a need to further develop terminology, definitions and nomenclature, especially within the international community.

Other speakers called for the development of a framework and tools that support the design of beneficial nanotechnology while minimizing adverse impacts. They called for the development of a multi-criteria evaluation system, and for the application of safe-by-design concepts. One speaker suggested that, where possible, nanoparticles and nanostructures found in nature should be used.

3.3 Public Awareness and Education

Advances

There was broad agreement among stakeholders that public awareness and understanding of nanotechnologies and nanomaterials is key to responsible nanomaterials development. There have been a number of efforts to inform and educate the public and consumers on the issues surrounding the use of these technologies in Canada and abroad. In particular, the Government of Canada has established a public website, the NanoPortal, to provide a single-window access to the latest information on nanotechnology. In the US, the National Nanotechnology Initiative sustains outreach and education programs to inform the public, including K-12 students, about the opportunities and impacts of nanotechnology. The European Commission requires the labelling of nanomaterials in certain products in order to ensure that consumers can make better-informed purchasing decisions.

Gaps

Several participants emphasized that the risks and benefits of nanomaterials must be quantified and better communicated to consumers so that they can make informed decisions. Others also stated that a lack of education and awareness building means that consumer trust in regulations is low; it was suggested that the public may believe there is no nanomaterials regulatory system in place.

One proposed solution was the use of labelling as an educational tool in Canada, although there was some disagreement on this issue. Some workshop participants felt labelling could create a negative image of products containing nanotechnology, while others felt it could help build awareness, trust, and offer tools for informed decisions.

3.4 Stakeholder Engagement

Advances

According to workshop participants, engaging stakeholders in the regulation nanomaterials is central to the Canadian Chemicals Management Plan (CMP). Stakeholders contribute to the CMP through regular public information sessions and consultations. (Information on stakeholder engagement can be accessed on the Government of Canada website at:
http://www.chemicalsubstanceschimiques.gc.ca/plan/progress_report-rapport_etape-eng.php)

The CMP provides a mechanism for all stakeholders to get engaged in the regulation of nanomaterials, and is designed to be an open and transparent process.

Gaps

The need for broader engagement of Canadian stakeholder groups was identified by many workshop participants.

4.0 Key Themes and Priorities for Action

Based on the presentations and discussions during the workshop, ten priorities for action to advance the safe development of engineered nanomaterials were identified by Pollution Probe. These priorities reflect the views of stakeholders at the workshop. The aim in presenting these actions is to stimulate broader discussion between governments, industry and civil society on how we can realize the benefits of nanotechnology while addressing human and environmental risks and consumer concerns.

The priorities that emerged from the workshop presentations and discussions include the need to:

1. Develop a coordinated, Canada-wide nanomaterials research program, incorporating the following elements:
    - Develop robust analytical techniques for detection, quantification and characterization of nanomaterials in various matrixes – for example in consumer products - and in the environment.
    - Develop improved forecasting models for the fate of nanomaterials in the environment.
    - Gather data on nanomaterials exposure – both human and environmental - that reflects real-world conditions. In particular, there is a need for data on toxicity.
    - Provide funding for independent and transparent nanotechnology research; for example, by publicly-funded laboratories and universities

2. Facilitate the effective use of existing data by removing barriers to data sharing and increasing access to industry data and government curated data. Validate existing data sets, which vary in quality.

3. Develop a comprehensive, Canada-wide inventory of existing engineered nanomaterials and products containing nanomaterials already on the market.

4. Support the development of common terminology, definitions, nomenclature and classification of nanomaterials within the international community. A lack of an internationally recognized nomenclature system creates challenges for the assessment and registration of nanotechnology, and is a barrier to risk assessment. In terms of categorization, there is some discussion about whether classification should be based on chemical composition or on behavioural properties of nanomaterials.

5. Enhance research on risk assessment, with a focus on collecting data on hazard. Consider multiple approaches to risk assessment, including alternatives assessment methods. Enhance proactive risk assessment of nano-enabled products before they go to market.

6. Develop tools for quantifying and assessing risks and benefits of nanomaterials, using a multi-criteria evaluation approach, with the goal of determining whether specific uses of nanotechnology result in net social benefits.

7. Facilitate interdisciplinary collaboration and learning from international efforts in the areas of research, risk assessment and management as well as policy development on nanomaterials.

8. Develop a public engagement strategy on nanomaterials, focusing on the following elements:

- Transparent and accessible information on the risks and benefits of nanotechnology and nanomaterials, allowing consumers to make informed purchasing decisions and promoting rational dialogue on risks and benefits in order to avoid polarizing debates.
- Building consumer trust in the regulation of nanotechnology through effective risk communication.
- Improving public understanding of the nanomaterials regulatory system.
- Increased funding to civil society groups to help with knowledge translation, public awareness-raising, outreach and education.

9. Study and implement safe nanomaterials routes, and implement safer-by-design nanoproduct concepts.

10. Conduct a study on the potential of increased costs of nanomaterial-enabled products to assess their accessibility by low-income and vulnerable people.