

Conseil des académies canadiennes

News Release

July 10, 2008 — Expert Panel Concludes there is not Enough Information to Assess the Safety of Nanomaterials

OTTAWA – An expert panel appointed by the Council of Canadian Academies has concluded that too little is known to assess the overall human and environmental risks posed by the introduction nanomaterials and nanoproducts into society. However, the panel did not identify any evidence that nanoproducts currently on the market in Canada present risks that cannot be addressed through available risk management strategies.

"The panel sought to assemble the existing science, and understand what it implies about the hazards presented by nanomaterials, what risks they present to human health and our environment, and how we can best manage these risks given the current uncertainties and key gaps in knowledge," said University of of Toronto professor Pekka Sinervo, chair of the expert panel.

The report, requested by Health Canada (in consultation with several other federal agencies), was prepared by a panel of 15 experts who are engaged in the creation and application of nanomaterials, assessment of the risks they may present, and public policy issues related to health and environmental regulation. The report was in response to the question, "What is the state of knowledge with respect to existing nanomaterial properties and their health and environmental risks, which could underpin regulatory perspectives on needs for research, risk assessment and surveillance?"

What are nanomaterials?

Nanomaterials may be defined as materials having one or more dimensions on the nanoscale — i.e., between 1 and 100 nanometres (nm). A nanometre is one millionth of a millimetre — approximately 100,000 times smaller than the diameter of a human hair. A red blood cell is approximately 7,000 nm in diameter.

As the particle size of certain materials is reduced to the nanoscale, they can exhibit novel and useful properties. Gold, for example, in its bulk form, is inert and resistant to oxidation, but nanoscale gold exhibits a remarkable ability to oxidize carbon monoxide — making it a novel candidate for use in car exhaust systems. A second example — titanium dioxide particles, well above the nanoscale, are responsible for the intense whiteness of many paints and toothpastes whereas the addition of nanoscale titanium dioxide to sunscreens results in their translucence once they are applied to the skin. This difference between nanomaterial properties and their bulk properties is what can make nanomaterials very useful, but these often surprising differences may also result in unanticipated behaviours in biological and environmental systems.

As of April 2008, there were over 600 nanotechnology-based consumer products including: sunscreens,

Science Advice in the Public Interest www.scienceadvice.ca anti-stain coatings on fabrics, antimicrobial features in washing machines and refrigerators various medical and electronic applications, among others.

The sheer diversity of possible nanomaterials, when combined with their unpredictable biological and environmental properties, makes it very challenging to assess the risks of nanomaterials and thus to design regulation to help manage possible risks. The report concluded that to date, there has been no identification of unique biological effects associated with exposure to nanomaterials, but there is still a poor understanding of the pathways by which these effects may occur.

The Canadian Regulatory Approach

The current risk assessment strategies that are used in health and environmental regulations in Canada comprise four steps: hazard identification, hazard characterization, exposure assessment and risk characterization. The application of these to nanomaterials will require new ways for measuring exposure, dose and response. The report concludes that there are, at present, inadequate data to inform quantitative risk assessments on nanomaterials. At most, only qualitative risk assessments are feasible. Moreover, changes in the potential for nanomaterials to cause harm at different stages — from production, through usage, to final disposal — implies the need for a full, life-cycle approach to risk assessment.

Uncertainties associated with risk assessment and risk management are typical in the introduction of new technologies and are not unique to nanomaterials. Such uncertainties have been managed within Canadian regulatory systems by taking a precautionary approach – giving priority to ensuring the safety of health and the environment. Since it is not possible, at present, to implement a robust and reliable "science-based" regulatory approach to nanoproducts, it is important that appropriate precautionary measures guide the scientific assessment of the risks and the selection of standards of safety. In so doing, a wide spectrum of stakeholders should be involved in determining the desired level of precaution when regulating the introduction of new nanomaterials and products to the market. The report finds that an adaptive management approach will be needed so that, as scientific research fills in our knowledge gaps, the decisions respecting the precautionary measures applied to nanoproducts can be revised.

Filling in the "Knowledge Gaps"

While the panel was not asked to make specific recommendations, it identified the following as key steps towards filling in existing knowledge gaps.

- International efforts are currently underway to develop standardized definitions and nomenclatures for nanomaterials but the process may take upwards of 10 years to complete. In the meantime, interim terminology and classification are needed to help regulators oversee this emerging group of materials and products.
- In conjunction with classification, new tools and standards are needed to ensure that the exposure
 of both the public and workers to nanomaterials is consistently and reliably monitored.
- Current regulatory triggers (based on the amount and chemical structure of materials) will need to be revised in order to identify those nanomaterials entering the market that may require regulatory oversight.
- The diversity in both material type and usage of nanomaterials, the magnitude of scientific research that is needed, and the increasing presence of traded products that contain nanomaterials, will require governments to work collaboratively both within Canada and internationally.

Research is needed to identify the properties of a nanomaterial that enable it to elicit an adverse biological response and, in light of this, to identify appropriate regulatory responses regarding nanomaterial exposure.

"The panel's report builds on the work underway internationally to better understand the benefits and risks presented by engineered nanomaterials," said Dr. Sinervo. "I believe that this report will be a valuable and unique contribution, given its focus on what science tells us about the risks associated with these unusual materials and how we can manage these risks responsibly."

The complete findings of the expert panel have been conveyed to the federal government and are available on the Council's website, <u>www.scienceadvice.ca.</u>

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