

## CANADA

### *Highlight of Developments since the 2<sup>nd</sup> Meeting of the WPMN*

The following activities have taken place since the 2<sup>nd</sup> meeting of the OECD Working Party on Manufactured Nanomaterials in April 2007:

- Environment Canada and Health Canada hosted a multi-stakeholder workshop to consult with industry, non-governmental organizations, academia, and other interested parties on the proposed approach to a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* (see Section 1).
- Environment Canada issued an advisory note on the application of the *New Substances Notification Regulations (Chemicals and Polymers)* for nanomaterials (see Section 1).
- Industry Canada, in conjunction with Environment Canada, Health Canada, and the Canadian Food Inspection Agency completed a contract study to identify US companies exporting nanotechnology-related products to Canada (see Section 2).
- In the area of scientific research, funding for two environmental effects projects has been approved and there are more opportunities to obtain funding for environmental and health related research on nanotechnology. Several National Research Council Institutes are collaborating to exploit multi-disciplinary strengths to focus on fundamental R&D topics which underpin EHS research. (See Section 5).
- In the area of policy research the Council of Canadian Academies has begun an assessment of the current state of knowledge of potential human health and environmental risks of nanotechnology. The Canadian Institutes of Health Research, in conjunction with various federal government departments, is planning a workshop to examine the nano ethical, economic, environmental, legal, and social issues. (See Section 5).

## 1. Regulatory Developments in Canada

### Federal government actions

- A. In September 2007, Environment Canada and Health Canada hosted a multi-stakeholder workshop on a proposed approach for a regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999*. The one-day meeting brought together members of industry, non-governmental organizations, academia, and other interested parties to obtain their feedback on the overall proposed approach and the possible options for information gathering initiatives (see Section 2). The final workshop report will be issued in late November 2007.

The proposed approach to develop a regulatory framework for nanomaterials consists of two phases with near and longer term objectives.

Phase 1 (started fall 2006):

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

Phase 2 (2008 – 2010):

1. Resolution of standard nomenclature and terminology by the ISO.
2. Consider establishing specific data requirements for nanomaterials under the NSNR.
3. Consider the use of Significant New Activity notices for substances already on the DSL.

- B. On July 16, 2007, Environment Canada issued an advisory note informing manufacturers and importers of nanomaterials of their regulatory responsibilities for nanomaterials under the *New Substances Notifications Regulations (Chemicals and Polymers)*. The advisory note provides information describing nanomaterials and which nanomaterials are subject to the current regulations. The advisory note can be found at [http://www.ec.gc.ca/substances/nsb/eng/a200706\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml).
- C. A nanotechnology workshop for the Health Portfolio was held in March 2007. Participants from Health Canada, the Public Health Agency of Canada, and the Canadian Institutes of Health Research met with invited experts to discuss the basis for a Health Portfolio Strategy on Nanotechnology. A Health Portfolio Nanotechnology White Paper will be produced based on a previously developed Health Portfolio Issue Paper and the findings of the workshop.
- D. An interdepartmental senior management committee is in place to engage federal science and technology departments. The committee has drafted a federal action plan for a coordinated and consistent approach to the regulation of nanotechnology in Canada. The plan includes recommendations to senior management to:
- Endorse and support the management structure for efforts on nanotechnology;
  - Enhance partnerships and linkages with industry, academia, and laboratories; and
  - Continue to participate actively in international efforts.
- E. A Federal Workshop on the Health and Environmental Implications of Nanoproducts (March 2006) brought together senior regulatory program managers, hazard and risk evaluators, and researchers to discuss regulatory science needs for nanotechnology. This workshop led to the formation of a Federal Working Group to:
- Develop consistent approaches to testing, assessment and management of nanomaterials;
  - Cooperate in research and testing of nanomaterial properties and effects;
  - Ensure adequate resourcing of Canada's participation in international activities; and

- Ensure no duplication of efforts with respect to developing the necessary science to assess substances and products of nanotechnology.

## **2. Developments on Voluntary or Stewardship Schemes in Canada**

Information gathering schemes aim to obtain information on nanomaterials in order to help direct the development of regulations, research, and risk assessments. Several options are being considered for information gathering initiatives: a voluntary program, a mandatory program, and a blend of voluntary and mandatory programs. A proposal for an information gathering initiative is expected to be issued in January 2008 based on feedback from the multi-stakeholder workshop (see Section 1).

The information gathering scheme will focus efforts on obtaining information on nanomaterials from industry and on building a knowledge base to inform risk assessment and management approaches. The objectives of the program would include:

- Identification of nanomaterials in Canadian commerce.
- Facilitated acquisition of information in industry possession.
- Provision of guidance on appropriate testing to identify potential health and environmental impacts of nanomaterials.

The Canadian approach will be informed by discussions within Steering Group 5 of the WPMN. The current tasks in preparation for a Canadian information gathering initiative:

- Considering incentives that would encourage notification within the initiative timeframe.
- Developing consultation documents to engage industry, the public, and other stakeholders.
- Targeting program launch in the first 6 months of 2008.

### Nanotechnology Market Penetration in Canada

There is a limited understanding of the current Canadian market for nanotechnology. A formal use pattern survey and product inventory has not been conducted for Canada; however, Industry Canada has undertaken some preliminary investigations.

Industry Canada has examined its Strategis database and conducted independent web searching to identify Canadian companies engaged in nanotechnology. Industry Canada also contracted a study, in collaboration with Environment Canada, Health Canada, and the Canadian Food Inspection Agency, to investigate US companies exporting nanotechnology-related products to Canada. The final report can be at [http://www.ic.gc.ca/epic/site/aimb-dgami.nsf/en/h\\_03459e.html](http://www.ic.gc.ca/epic/site/aimb-dgami.nsf/en/h_03459e.html).

Analysis of all the data collected through these projects identified 79 domestic companies with 107 distinct product lines and 63 US companies which include Canada in their business with 127 distinct products lines. Of the 234 product lines, 151 had nanomaterial identity information available on-line and these products represented 88 distinct nanomaterials with 85 distinct uses. The products included a range of constituent nanomaterials, including elemental, alloy, carbon-based, and mineral nanomaterials. Furthermore, these nanomaterials represent a range of

industrial sectors including consumer products, life sciences, chemicals, plastics, semiconductors, construction, transportation, security, energy, earth science and environment.

### 3. Risk Assessment Decisions

A small number of notifications have been received by some regulatory programmes.

- Industrial or commercial chemicals
  - Recently, the New Substances Program of Environment Canada and Health Canada received notification for a substance identified as a nanomaterial. This substance is currently under review by the two departments.
- Pharmaceuticals
  - Two nanomedicines have received approval from Health Canada under the current regulations and policies.
- Pesticide applications
  - Some inquiries have been made, but no notifications have been submitted.
- Food related applications
  - Some food related applications in the natural health products field are currently under review by Health Canada.
  - No notifications on food additives or food packaging have been received to date.
- Others
  - No notifications with respect to fertilizers, veterinary biologics, or animal feed have been received to date.

### 4. Developments of Good Practice Documents

No activities to report on this topic.

### 5. Research in Canada

#### Scientific research

Research on human health and environmental effects in Canada is limited, but efforts are currently ongoing to strengthen both government and academic initiatives, especially those emphasizing collaborations between these two groups of researchers.

- Environment Canada (EC) and Health Canada (HC) are supporting research proposals addressing environmental fate of nanomaterials. In October 2007, two projects on environmental effects have received funding from the Strategic Grants Program of the Natural Sciences and Engineering Research Council. These projects will involve a multi-university approach with input and financial support from EC, HC, and Agriculture and Agri-Food Canada.
- Natural Sciences and Engineering Research Council and the Canadian Institutes for Health Research are encouraging the inclusion of health and environmental impacts components for research proposals involving nanotechnology. In a special call for proposals, the National Research Council of Canada and the Business Development Bank of Canada have targeted nanotechnology research in part related to the environment. The competition is currently underway.

- The National Research Council of Canada has launched new R&D initiatives which support collaborative projects between Institutes ([http://www.nrc-cnrc.gc.ca/institutes/index\\_e.html](http://www.nrc-cnrc.gc.ca/institutes/index_e.html)). These cross-Institute Programs in Nanotechnology exploit the multi-disciplinary strengths of the NRC with focus on fundamental R&D topics which underpin EHS research; topics such as metrology in support of nanotechnology. Proposals have been selected from competition and research work will be underway this fiscal year.

#### Policy research

- The Council of Canadian Academies is a non-profit organization which acts as a source of independent, expert assessment of the science underlying pressing issues and matters of public interest. The Council is undertaking an assessment of the current state of knowledge regarding the health and environmental risks potentially associated with nanotechnology. This work began in February 2007 and is expected to be completed in the spring of 2008.
- Canadian Institutes for Health Research, in partnership with Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council of Canada, Health Canada, Environment Canada, Industry Canada, and other federal departments, is planning a workshop on nanotechnology in early 2008. The objective of the workshop will be to promote discussion on developments in the field of nanotechnology and the policy challenges that they may present, i.e., nano ethical, economic, environmental, legal, and social issues (NE<sup>3</sup>LS). The workshop will also seek to set research priorities in the field of nanotechnology and health impacts.

## **6. Public and Stakeholder Consultations**

Environment Canada and Health Canada hosted a multi-stakeholder workshop on a proposed regulatory framework for nanomaterials under the *Canadian Environmental Protection Act, 1999* involving industry, non-governmental organizations, academia, and other interested parties. Additional consultative meetings will be conducted as part of the normal process in the development of a regulatory regime for nanomaterials.