

Attachment 4:

Overview of international activities addressing regulation of industrial nanomaterials.

US government (Environmental Protection Authority) approach to regulation of industrial nanomaterials:

Chemical Nanoscale Materials

Many nanomaterials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). This law provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects against unreasonable risks to human health and the environment.

For example, TSCA requires manufacturers of new chemical substances (i.e., those not on the [TSCA Chemical Substances Inventory](#)) to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can require reporting or development of information to assess existing chemicals already in the marketplace. Additionally, EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled.

One of the key questions for manufacturers and importers is determining whether a given nanoscale material is already listed on the TSCA Inventory or if it is a new chemical requiring premanufacture notification to the Agency. On January 28, 2008, EPA released the [TSCA Inventory Status of Nanoscale Substances – General Approach \(2008\) \(PDF\)](#), (7 pp, 37K), describing EPA's current thinking regarding whether a nanoscale material is a "new" or "existing" chemical substance under TSCA.

EPA has received and reviewed numerous new chemical notices under TSCA for nanoscale materials including carbon nanotubes. The Agency has taken steps to control or limit exposures to these chemicals, including: limiting the uses of the nanoscale materials, requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators, and limiting environmental releases.

The Agency has also required testing to generate health and environmental effects data where appropriate. EPA has permitted limited manufacture of new chemical nanoscale materials through the use of administrative orders or Significant New Use Rules under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the protective equipment and environmental release limitations discussed above).

To complement and support EPA's new and existing chemical programs under TSCA, the Agency developed a [Nanoscale Materials Stewardship Program \(N MSP\)](#). The N MSP will help provide a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and contribute to an improved understanding of risk management practices for nanoscale chemical substances (nanoscale materials).

Taken from: <http://www.epa.gov/oppt/nano/>

Canadian government (Environment Canada) approach to regulation of industrial nanomaterials:

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.

Taken from: http://www.ec.gc.ca/substances/nsb/pdf/nanoproposition_e.pdf

UK government (Environmental Protection Authority) approach to regulation of industrial nanomaterials:

The UK Government and the European Commission have commissioned several [studies of current legislation](#) affecting the development and marketing of nanomaterials. These have found that the existing regulatory framework is broadly adequate but that some changes are needed and there may be some regulatory gaps. Although progress is being made in improving our understanding of potential risks from nanomaterials, our knowledge in many areas is not yet sufficient to enable us to determine if there are real regulatory gaps or how they should be remedied. In addition, our understanding has still to reach the stage at which we can be confident that methods of identifying hazards and evaluating risks are adequate, and thus that businesses are able to carry out reliable risk assessments of new products.

The Government is committed to ensuring that legislation is proportionate and evidence- and risk-based and focused on the specific properties and functionalities of nanomaterials as well as their size. The regulatory issues are not unique to the UK and the Government is working with –

- . The [OECD](#) to share information and agree priorities for regulation; and
- . The [EU](#) to ensure that EU legislation is amended in a timely and appropriate manner, where necessary following advice from the relevant EU scientific advisory committees.

Hilary Benn, the Secretary of State for Environment, Food and Rural Affairs wrote to the European Commission in 2008 to encourage it to expedite actions to update its legislation. Since then -

- . Agreement has been reached on updating and amending the [EU Cosmetics Directive](#) to take account of nanomaterials. It will require prior notification and labelling of products containing nanomaterials;
- . Negotiations have begun on a proposal to update the [Novel Foods Regulation](#) and make it clear that nanomaterials fall within its scope; and

A working group has been established that is considering the applicability of the new EU Chemicals regime, the [REACH Regulation](#), to nanomaterials. For example, it will consider the need for different weight thresholds for nanotechnologies. In addition, methods for identifying hazards and evaluating risks of substances at the nano-scale need to be further refined over the next few years.

Taken from: <http://interactive.bis.gov.uk/nano/cross-cutting-issues/managing-risks-and-uncertainties/>

EU government (REACH) approach to regulation of industrial nanomaterials:

The first registration deadline under REACH (30 November 2010) applies to substances manufactured or imported at 1000 tonnes or more per year. The registrations of nanomaterials in this tonnage band will help to generate more information useful for the assessment of risks. [The European Chemicals Agency \(ECHA\)](#) receives the registrations and the Agency plays a central role in the collection, evaluation and dissemination of information on substances and preparations, including nanomaterials.

Moreover, nanomaterials that fulfil the criteria for classification as hazardous under [Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures](#) must be classified and labelled. Many of the related provisions, including safety data sheets and classification and labelling apply already today, independently of the tonnage in which the nanomaterials are manufactured or imported. Substances, including nanomaterials, meeting the classification criteria as hazardous must be notified to ECHA by 1 January 2011.

In close co-operation with the [CARACAL](#) subgroup on nanomaterials ("CASG Nano", composed of Member States and stakeholder experts) the Commission is elaborating advice on how nanomaterials should be managed in accordance with REACH. The first paper [Nanomaterials in REACH](#) [236 KB] provides an overview of how the provisions of REACH apply to nanomaterials. Additional papers are planned on registration and classification and labelling. These papers will be handed over to ECHA for integration into the relevant guidance documents.

Taken from: http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm