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Sustainable Nanotechnology Organization Conference

Legal Aspects/Policy Considerations

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Lots Going On

- Many global initiatives involving diverse governance aspects of nanoscale materials
- Many countries are struggling with defining nanoscale materials and addressing related definitional challenges
- Countries are also examining how best to assess risks from nanoscale materials, promoting sensible governance strategies, and maximizing opportunities

Global Governance Constructs

- Legislative Initiatives
- Regulatory Initiatives
- Voluntary Initiatives
  - Government -- NIOSH, EPA
  - Corporate Stewardship Initiatives (testing, “best practices,” related public-private initiatives)
  - Collaborative Initiatives -- OECD, NanoRisk Framework, to name a few
- Standard Setting Initiatives
  - ISO -- TC-229
  - ASTM -- E56
- *See* Attachment 1 for a global summary of these initiatives (too numerous to address here)
- *See* Attachment 2 article -- *Green Nanotechnology: Straddling Promise and Uncertainty*, *Natural Resources & Environment* (Fall 2009)

"Sustainability" Needs to Be Added to the Mix

- "Sustainable" nano depends on:
  - Clear identification of benefits
  - Standardization of methods to demonstrate these benefits through a life cycle assessment (LCA) approach
  - Broad societal acceptance

Defining Sustainability Clearly through Metrics

- Need an LCA Approach Tailored to Nano Products
  - Identifies/quantifies EHS implications of nano products
  - Assesses benefits unique to nano products
  - Addresses uncertainties unique to nano products
- Need performance/branding standards for sustainable nano products
- Need greater regulatory incentives that promote the commercialization of nano products
  - Pollution prevention “field” in TSCA PMN form is a good start, but more is needed

Sustainable Nano Also Needs

- Tax and other business incentives to commercialize nano products
  - TSCA Reform offers opportunities
- More research funding specific to sustainable nano
- Much greater societal acceptance
  - Stakeholders must make a more sustained effort to define and promote nano products
  - Federal government is doing more as part of the National Nanotechnology Initiative, but more is needed from industry and other stakeholders
- More members in SNO to nurture and support sustainable nano initiatives

THANK YOU

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Attachment 1

Canada

- Environment Canada proposed in 2008 a Section 71 notice
- In October 2011, Health Canada published a “Policy Statement on Health Canada’s Working Definition for Nanomaterials”
  - It is at or within the nanoscale (1-100 nm) in at least one external dimension, or has internal or surface structure at the nanoscale
  - It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena

Canada (cont'd)

- Industrial or commercial chemicals: Since March 2011, Canada has received five notifications for nano-related assessment
  - Significant New Activity (SNAc) provisions applied, requiring the submission of additional information and assessment
- Pharmaceuticals: A number of nanotechnology-based products in the areas of medical devices and drugs are currently under review
- Food-related applications: Six notifications received
  - Two letters of no objection issued
  - Other four are under review

Australia

- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) introduced the first regulatory program for "industrial nanomaterials" as of January 1, 2011
  - Working definition: Industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (*i.e.,* that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (*i.e.,* having an internal or surface structure at the nanoscale)
  - Included are:
    - Aggregates/agglomerates as nanostructured substances
    - Materials where size distribution shows 10% or more of a substance (based on number of particles) are at the nanoscale

Australia (cont'd)

- NICNAS is developing options to regulate nano-forms of existing chemicals
  - Plans stakeholder consultations in 2012
- The Department of Innovation, Industry, Science and Research, as part of the National Enabling Technologies Strategy, is assessing the feasibility of a nanotechnology product registry
  - The December 2011 report by the Centre for International Economics concludes that the challenge presented by nanotechnology can be met through existing regulatory frameworks, making it difficult to see a nanoproducts registery delivering a net benefit to the community

Australia (cont'd)

- Safe Work Australia (SWA) is implementing the Nanotechnology Work Health and Safety Program, which is supported by:
  - Nanotechnology Work Health and Safety Advisory Group
  - Nanotechnology Work Health and Safety Measurement Reference Group

Australia (cont'd)

- SWA recommends the following label statements for products containing nanomaterials when the hazards are not fully characterized:
  - Contains engineered/manufactured nanomaterials. Caution: Hazards unknown
  - Contains engineered/manufactured nanomaterials. Caution: Hazards not fully characterized

France

- Published a February 17, 2012, “Decree regarding the annual mandatory reporting of nanoparticulate substances placed on the market”
  - Companies that manufacture, import, and/or distribute a “substance with nanoparticle status” in an amount of at least 100 grams per year must submit an annual report with substance identity, quantity, and use information
  - The report will be due by May 1 for information about nanoparticle substances produced/imported/distributed during the prior year
  - The Decree is effective January 1, 2013, so a report containing 2012 data will be due by May 1, 2013

France (cont'd)

- An August 10, 2012, order establishes the information to be provided to determine the identity of the declarant, the identity of the nanoparticle substance, its uses, and the quantities of the nanoparticle substance produced, distributed, or imported
- On September 6, 2012, Carl Schlyter, a Swedish Green member of the European Parliament, filed a challenge in the EU General Court against the European Commission (EC) for its refusal to disclose an opinion on the French law on nanomaterials
  - Schlyter said he filed the case because regulation of nanomaterials is "highly political" and it should be clear what objections the EC raised how the French law was subsequently modified

Japan

- Japan's Ministry of Economy, Trade and Industry (METI) established a Committee on Safety Management for Nanomaterials
  - The Committee will focus on risks caused by nanomaterials, and study appropriate management procedures for nanomaterials considering the actual usage and life cycles
  - The Committee held its first meeting on December 2, 2011
  - The Committee will compile an interim report "around spring to summer in 2012"
- METI calls on industry to report voluntarily their safety data and management activities

Korea

- National Nano-safety Master Plan (2012-2016) covers nanomaterials, nanotechnology, nanoproducts, and occupational safety
- The Ministry of Knowledge and Economy prepared a “Guidance on Safe Management of Nanotechnology-Based Product”
- The Ministry of Environment developed a guidance on the occupational safety management of nanomaterials
- The Ministry of Environment began a voluntary survey on the production, use, import, and export volumes and use patterns of manufactured nanomaterials

Switzerland

- Currently preparing a guidance document concerning the requirements for self-supervision by manufacturers and importers regarding synthetic nanomaterials under the existing Swiss chemicals law
- On April 25, 2012, the Federal Council continued the action plan for synthetic nanomaterials through the end of **2015**
  - The primary focus is on developing a methodical basis for nano-specific provisions
  - By the end of **2014**, a new report will provide an update on the situation

United States -- EPA

- In June 2011, the U.S. Environmental Protection Agency (EPA) issued a proposed policy on nanoscale materials in pesticide products
  - EPA proposed obtaining information concerning nanoscale materials using either Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which concerns adverse effects reporting, or a data call-in (DCI) under FIFRA Section 3(c)(2)(B)
  - EPA also proposed to apply an initial presumption that nanoscale ingredients are potentially different from those conventionally sized counterparts
    - The presumption could be rebutted on a case-by-case basis

United States -- EPA (cont'd)

- On December 1, 2011, EPA announced a conditional registration for a nanosilver-based antimicrobial pesticide product that will be incorporated into textiles
  - As a condition of registration, EPA is requiring the registrant, HeiQ, to conduct a number of studies within four years
  - On January 26, 2012, the Natural Resources Defense Council (NRDC) filed a lawsuit challenging the conditional registration
  - Specifically, NRDC urges the court to set aside the authorization until the data EPA has requested are generated, submitted, and reviewed

United States -- EPA (cont'd)

- In May 2011, EPA promulgated a significant new use rule (SNUR) for the chemical substance identified generically as multi-walled carbon nanotube (CNT), which was the subject of premanufacture notice (PMN) P-08-199
- In December 2011, EPA proposed SNURs for 17 substances that were the subject of PMNs, including seven whose reported chemical names include the term "carbon nanotube" or "CNT"

United States -- EPA (cont'd)

- EPA's January 20, 2012, Regulatory Agenda --
  - EPA is developing a Toxic Substances Control Act (TSCA) Section 4(a) test rule to require manufacturers and processors of the multi-walled CNT described in PMN P-08-199, certain clays (*e.g.*, kaolin (including halloysite) and bentonite (including montmorillonite)), alumina, and spray-applied nanomaterials to conduct testing for health effects, ecological effects, and environmental fate, as well as provide material characterization data
  - EPA is developing a SNUR under TSCA Section 5(a)(2) for nanoscale materials, as well as a TSCA Section 8(a) rule to require reporting and recordkeeping. It is widely believed that EPA has unofficially given up on the nanomaterials SNUR and is considering alternative approaches

United States -- FDA

- In June 2011, the U.S. Food and Drug Administration (FDA) issued draft guidance concerning whether a product involves nanotechnology
  - Would apply to all FDA-regulated products, including foods, cosmetics, drugs, devices, veterinary products, and tobacco products
- On April 20, 2012, FDA announced two draft guidance documents
  - Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives
  - Guidance for Industry: Safety of Nanomaterials in Cosmetic Products

United States -- FDA (cont'd)

- On July 9, 2012, President Barack Obama signed the Food and Drug Administration Safety and Innovation Act (P.L. 112-144), which includes a section concerning nanotechnology
- The Act directs the Secretary of Health and Human Services to "intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under the Federal Food, Drug, and Cosmetic Act" or other statutes administered by FDA

United States -- CPSC

- The Consumer Product Safety Commission's (CPSC) 2010 report to Congress includes three research activities:
  - **Nanotechnology Annual Data Update (Consumer Product Database):** CPSC is developing an internal database that lists specific products and the materials contained in the products
  - **Nanomaterials in Aerosol Products:** The National Institute for Occupational Safety and Health (NIOSH) expects to complete its evaluation of aerosols released from a spray product and submit a final report to CPSC in 2011; CPSC expects to continue this work to test similar products
  - **Nanosilver in Consumer (Children's) Products:** CPSC entered into new agreements with NIOSH and EPA to evaluate potential exposures to consumers from use of nanosilver-enabled products

United States -- CPSC (cont'd)

- CPSC's FY 2012 budget request sought funding for these activities and:
  - A study concerning CNTs in selected products;
  - Enhancement of the National Library of Medicine Household Products Database to provide information on nanomaterials in consumer products; and
  - A literature search on consumer exposure to nanomaterials from treated products

United States -- NanoRelease Project

- The NanoRelease Project is organized by the ILSI Research Foundation, and is supported by EPA, Environment Canada, Health Canada, the American Chemistry Council, the Society of Chemical Manufacturers & Affiliates, the National Institute of Standards and Technology, the Adhesive and Sealant Council, and the American Cleaning Institute
- The NanoRelease Project is intended to support the development of methods to understand the release of nanomaterials used in products

United States -- NanoRelease Project (cont'd)

- The NanoRelease Project completed Phase 1 in 2011, selecting multi-walled CNTs in polymers for evaluation
- In Phase 2, three Task Groups are evaluating:
  - Measurement methods;
  - The effect of materials selected on release rates; and
  - Identifying the key exposure/release scenarios
- Phase 3 is scheduled to begin in late 2012, with a "round robin" approach to inter-laboratory testing using a reference nanomaterial-matrix and positive controls for the study of multi-walled CNTs released from selected polymers

Other International Initiatives

- Organization for Economic Co-operation and Development (OECD):
  - Two Working Parties:
    - Working Party on Manufactured Nanomaterials (WPMN) (Chemicals Committee)
    - Working Party on Nanotechnology (WPN) (Committee for Scientific and Technological Policy)
- Approximately 100 countries engaged (member or “active” relationship)
- Forum for intergovernmental cooperation on environment

Other International Initiatives (cont'd)

- International Organization for Standardization (ISO)
  - Technical Committee 229 -- Nanotechnologies
  - Four Working Groups
    - JWG1 -- Terminology & Nomenclature (Canada)
    - JWG2 -- Measurement & Characterization (Japan)
    - WG3 -- Health, Safety & Environment (U.S.)
    - WG4 -- Material Specification (China)

Other International Initiatives (cont'd)

- Key ISO Activities: ISO Core Terms (80004-1)
  - Nanomaterial: Material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale. Term includes:
    - Nano-object: Material with 1, 2, or 3 external dimensions in the nanoscale
    - Nanostructured material: Material having internal or surface nanostructure
    - Nanostructure: A composition of inter-related constituent parts in which one or more is a nanoscale region

Other International Initiatives (cont'd)

- Global Plan of Action of the Strategic Approach to International Chemicals Management
  - Switzerland proposed that the sound management of nanotechnologies and manufactured nanomaterials be added to the Global Plan of Action
  - The proposal was considered at the third International Conference on Chemicals Management, held September 17-21, 2012

Business Issues

- Insurance
  - Insurers and reinsurers manage risk and are keenly aware of nanotechnology developments
  - Insurance risk includes:
    - Product liability
    - Worker compensation
    - Environmental impact
    - Professional liability

Business Issues (cont'd)

- Insurance companies have limited experience with the science and engineering of nanotechnology
- Few studies regarding human exposures to nanomaterials
- No (or few) human toxicological or epidemiological studies
- Currently, there are limited methods for measuring and classifying risks, but tools are more available now than before

Business Issues (cont'd)

- There have been many comparisons of certain nanomaterials to asbestos
  - Long latency period before discovery of damage
  - Relative ease of pulmonary entry
- Research has shown that multi-walled CNTs can penetrate the lining of the lung*
- Evolving research exploring the health implications of nanomaterial exposure in humans

* Earlier studies show MWCNTs injected into the lining of abdominal cavity of mice cause inflammation and granulomas suggestive of onset of mesothelioma, similar to that of other durable fibers, including asbestos.

Business Issues (cont'd)

- Litigation risk
  - Tort claim
    - Proof of causation is a significant hurdle
    - Medical monitoring claim
    - "No injury" claim
  - Product liability
    - May prompt more disclosure

Minimize Risk

- Keep abreast of developments -- monitor regulatory developments
- Keep abreast of scientific developments pertinent to nanotechnology
- Review contracts along supply chain
- Review insurance policies
- Know your clients' operations and be prepared to address nano issues that may arise from diverse stakeholders

Resources

- U.S. Environmental Protection Agency -- www.epa.gov/ncer/nano/questions/index.html
- National Nanotechnology Initiative -- www.nano.gov
- American Bar Association -- Nanotechnology Program – http://www.americanbar.org/groups/environment_energy_resources/projects_awards/nanotech.html
- Bergeson & Campbell, P.C. -- Website and Nano and other Emerging Chemical Technology Blog – www.lawbc.com; www.nanotech.lawbc.com
- National Institute for Occupational Safety and Health -- http://www.cdc.gov/niosh/topics/nanotech