

Nanotech Commercialization Conference

State of the Union -- Nanotechnology Environmental Health Safety 2012

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Overview

- United States
 - U.S. Environmental Protection Agency (EPA)
 - Proposed policy on nanoscale materials
 - Conditional registration for nanosilver product
 - Significant New Use Rules (SNUR) for carbon nanotubes
 - Regulatory Agenda items
 - NanoRelease Phase 2
 - National Institute for Occupational Safety and Health (NIOSH) Safe Nano Design Workshop
 - State Initiatives

Overview (cont'd)

■ International

➤ Canada

➤ European Union (EU)

- Recommendation on definition of nanomaterial
- Cosmetic labeling

➤ France

- Mandatory reporting scheme

➤ Organization for Economic Cooperation and Development (OECD)

United States -- EPA

- In June 2011, 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 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 February 13, 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

United States -- NanoRelease

- The NanoRelease Project is organized by Dr. Richard Canady, 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 (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

NIOSH -- Safe Nano Design Workshop

- The NIOSH Prevention through Design Program and Nanotechnology Research Center will hold an August 14-16, 2012, workshop entitled “Safe Nano Design: Molecule » Manufacturing » Market”
- Participants will provide input into the safe commercialization of nano products resulting in the development of guidelines for the safe synthesis of nanoparticles and associated products, using a Prevention-through-Design approach

State/Local Initiatives

- California -- Implementation of Green Chemistry Initiatives
 - Nanomaterial Hazard Trait
 - The Office of Environmental Health Hazard Assessment's (OEHHA) January 2012 final regulations do not specifically mention nanomaterials and nanoparticles
 - Definitional challenges
- California DCIs
 - January 2009 -- Carbon nanotubes
 - December 2010 -- Nano silver; nano zero valent iron; nano cerium oxide; nano titanium dioxide; nano zinc oxide; and quantum dots

State/Local Initiatives (cont'd)

■ Other States/Localities

- Maine -- Air Toxics Priority List -- Developed in 2007 included particulate matter from nanotechnology
- Massachusetts, Pennsylvania, South Carolina, Washington -- Nanotechnology is identified as an “emerging contaminant of concern”
- Wisconsin
 - Previous legislation called for creation of a nanomaterial registry and development of new legislation to address risk issues
 - February 2012 bill would create nanotechnology information hub and nanotechnology council

State/Local Initiatives (cont'd)

- Other States/Localities

- Berkeley, CA -- City Council nanomaterial disclosure law
- Cambridge, MA -- Nanomaterial information collection

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

EC Adopts Definition Recommendation

- On October 18, 2011, the European Commission (EC) adopted a Recommendation on the definition of a nanomaterial
 - “Invites” Member States, EU agencies, and economic operators to use the definition “in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies”
 - The EC will use the definition primarily to identify materials for which special provisions might apply (*e.g.*, for risk assessment or ingredient labeling)
 - By December 2014, the EC will review the definition “in the light of experience and of scientific and technological developments”

EU Regulation on Cosmetic Products

- Cosmetics legislation Regulation (EC) No. 1223/2009 on cosmetic products entered into force on January 22, 2010
- Noteworthy because it is the first EU rule to include a provision explicitly requiring the review of nanomaterials
- Starting July 2013, safety and labeling requirements apply to cosmetic products containing nanoscale materials (defined as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”)

France Mandatory Reporting Scheme

- French authorities developed two texts dealing with a national commitment to introduce a compulsory declaration scheme for nanomaterials
 - The first, which was released in final on February 17, 2012, is a decree defining how such a law would be applied
 - The second, which provides the information requirements that companies will have to meet to fulfill their obligations under the declaration, was open for consultation until the end of March 2012
- The first declarations covering nanomaterials produced, imported, and distributed in France in 2012 are expected in 2013

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

OECD (cont'd)

- On December 3, 2010, OECD posted two documents in its series on the safety of manufactured nanomaterials:
 - *Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories* -- Compares existing published guidelines regarding the use of nanomaterials at the laboratory scale, including the manufacture and the use of products in industrial, institutional, and commercial settings
 - *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision* -- Provides the list of representative manufactured nanomaterials and the list of endpoints for human health and environmental safety addressed by the Sponsorship Programme for the Testing of Manufactured Nanomaterials

Thank You

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