



# Nanotechnology – An Outline Of Environmental, Health & Safety Regulatory Issues April 16, 2009

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# Basic Issues

- From a regulatory perspective, nanoscale materials are subject to the same regulations as any other materials
  - E.g., Nanomaterials are subject to regulation under TSCA in the U.S. and REACH in the EU, etc.
  - Just because “nano” is somewhere in the name doesn’t mean it is in some sort of legal “free zone”: all the normal regulatory questions should be asked
- More challenging questions are:
  - What does it mean for nanoscale materials to be subject to existing environmental, health and safety requirements?
  - Are existing requirements sufficient to address nanoscale materials, or do new rules need to be written?

# A Few Of The Questions Being Asked

- Should nanoscale versions of existing and already regulated bulk materials be subject to new or different regulatory scrutiny?
  - E.g., should they be considered “new” chemicals for regulatory purposes?
- Should products currently subject to relatively low levels of regulation (e.g., cosmetics, textiles) be subject to increased or different scrutiny if they include nanoscale materials?
- How to regulate in the absence of data?
  - Nanotechnology raises again the discussions about the pre-cautionary principle, barriers to innovation, etc.

# Selected U.S. Regulatory Activity

- The American Bar Association has written a series of “white papers” evaluating the regulation of nanomaterials under the major existing environmental statutes.
  - [www.abanet.org/environ/nanotech/](http://www.abanet.org/environ/nanotech/)
  - These papers have generated debate, particularly the one on TSCA.
  - ABA also working on a similar white paper regarding the regulation of nanomaterials under the Federal Food, Drug and Cosmetic Act
- EPA launched its voluntary Nanoscale Materials Stewardship Program to collect data on nanomaterials
  - As of the end of 2008, approximately 30 companies and trade associations had submitted information
  - Disappointment in the level and quality of participation may lead to more direct regulatory actions to obtain data

# Selected U.S. Regulatory Activity

## TSCA

- Discrete nanomaterials are “chemicals” subject to TSCA
- Key initial question: are nanoscale materials “new” chemicals subject to TSCA’s PMN requirements
  - EPA has indicated its intent to enforce filing of PMNs for carbon nanotubes as of March 1
    - EPA judges that most carbon nanotubes are chemical substances distinct from graphite and other bulk carbon materials
  - EPA issued a Significant New Use Rule in November 2008 that imposed limitations on two nanoparticles: siloxane modified silica and siloxane modified alumina
  - EPA issued a TSCA 5e consent order in 2008 allowing limited production of multi-walled carbon nanotubes, but requiring the company to conduct inhalation study on rats, required PPE, and other conditions

# Selected U.S. Regulatory Activity

- FIFRA
  - EPA has taken comments on a petition to classify nanoscale silver as a pesticide (which would trigger registration, labeling, etc.)
  - EPA Region 9 fined a company over \$200,000 in connection with claims that a nanosilver coating on computer peripherals killed bacteria
- FDA
  - FDA has been petitioned to prohibit and/or regulate the sale of cosmetics, particularly sunscreens, that contain nanoparticles
  - FDA has conducted public meetings regarding the regulation of nanomaterials in drugs, medical devices, cosmetics
  - Current view seems to be that FDA will generate guidance, but no new regulations
- California
  - In January 2009, Dept. of Toxic Substances Control sent notices to more than 2 dozen entities, seeking toxicity and physico-chemical data on carbon nanotubes

# Selected Regulatory Activity Outside the U.S.

- EU
  - REACH
    - Nanomaterials are “chemical substances” under REACH; No special provisions for the nanoscale version of bulk chemicals
    - 1-ton trigger for REACH registration might exclude many nanoscale materials (TSCA does not have 1-ton exclusion). EU Parliament’s Env. Committee has called for removing 1-ton threshold for nano
    - Working group currently reviewing whether special guidance is needed
  - Cosmetics
    - Recent revision to cosmetics legislation, due to go into force in 2012, includes specific provisions on nanoscale materials
- Canada
  - New rule requiring companies that manufactured or imported more than 1 kg. of a nanomaterial in 2008 to report certain information to the regulators
- Japan
  - Recently issued voluntary guidelines on the control of nanomaterials

# Looking Ahead

- In the U.S., the discussion over the regulation of nanomaterials will likely remain centered in TSCA and FIFRA, with continued attention to consumer products
  - EPA may begin using its TSCA information gathering authorities to seek more data
- The “no data/no market” REACH scheme may push the creation and submission of health and safety data on nanomaterials
  - The 1 ton threshold might limit data collection
- “TSCA reform” might be a vehicle for legislative action to regulate nano, but there are major competing priorities on the Hill (e.g., economy, health care, climate change, etc.)



# Looking Ahead

- Early regulatory focus is on information, information, information
  - What is it, what does it do (people, environment), where does it go, what does it do when it gets there?
  - Information will ultimately drive regulatory decisions: bad science makes bad law, so it pays to play
- Expect public scrutiny
  - You can either wait and react, or you can get ahead of the curve and communicate
- In the absence of regulatory action, there is our old favorite: toxic tort/product liability litigation as a risk management driver