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Nanotechnology
Managing EH&S Issues and Regulations with an Emerging Technology

Commercialization of Nanomaterials

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Quotes

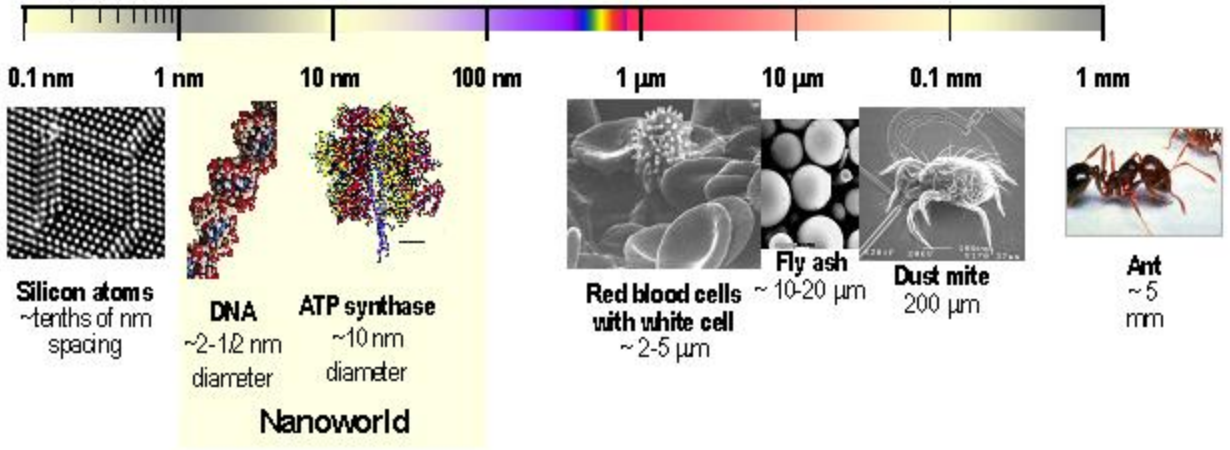
"The role of the infinitely small is infinitely large"

Louis Paste

"Few folks have mastered the fine art of filtering useful wisdom out of oceans of hype"

Unknown

NANOTECHNOLOGY



What is Nanotechnology

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While many definitions for nanotechnology exist, the NNI* calls it "nanotechnology" only if it involves all the following:

- Research and nanotechnology development at the atomic, molecular or macromolecular levels, in the length scale of 1 – 100 nanometer range.
- Creating and using structure, devices and systems that have novel properties and functions because of their small and/or intermediate size
- Ability to control or manipulate on the atomic scale.

** National Nanotechnology Institute*

Nanoparticles (Ultrafine particles)

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- Nanoparticles:
  - Engineered
  - Intentionally produced
- Ultrafine particles
  - Naturally occur
  - Incidental products/materials of processes
    - Products of combination
    - Volcanic eruptions
    - Seal Mist
    - Welding process

Nanotechnology : Business and Investment

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Forces:

- Uncertainties: is the technology safe?
- Materials are being made / products are in the global market
- Media coverage
- Public engaging and taking more interest
- Activities/discussions globally (US/EU/AP)
- Civil society organizations engaging globally

Application of Nanomaterials

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- Coatings
- Composites
- Displays
- Solar Cells
- Diagnostics
- Drug delivery systems
- Sensors
- Clothing
- Memory Chips
- Pharmaceuticals
- Cosmetics
- Therapeutics
- Remediation

Why Nanoparticles?

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Unique Properties

Size

- Optical
- Electronic
- Color
- Scattering
- Surface Chemistry
- Mechanical
- Mobility

Surface Area

- Catalysis
- Reactivity
- Melting/Sintering
- Rheology
- Composites
- Adsorption
- Dispersion
- Weight Reduction

Nanotechnology: Questions Asked/Debated

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- Is Nanotechnology safe?
- Can the regulations that are in place handle nanomaterials?
- What are the EHS Best Practices being used?
- What data / information needs to be developed on nanomaterials?
- What are the exposures to nanomaterials?

Nanotechnology: Questions Asked/Debated (cont'd)

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- What is the appropriate PPE?
- How do we handle waste?
- How do we clean up spilled material?
- What constitutes an adequate hazard communication program?
- Do we need a special training program?

Nanotechnology Focus Areas / Topics Globally

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- Definitions, nomenclature and characterization
- Environmental impacts (hazard identification; hazard and exposure assessment methods)
- Human health effects (hazard identification; hazard and exposure assessment methods

Nanotechnology
Focus Areas / Topics Globally (cont'd)

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- Regulatory frameworks (information exchange)
- Toxicology testing (test methods, evaluation of methods)
- Communications / engagement / transparency

Federal Regulatory Oversight: EPA

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- EPA External Review Draft Nanotechnology White Paper
  http://es.epa.gove/ncer/nano/publicatoins/whitepaper12022005.pdf)
  - Released in December 2005
  - Expert peer review meeting in April 2006
- Office of Pollution Prevention and Toxics (OPPT) Nanoscale Materials Stewardship Program
- Additional stakeholder meetings planned in 2006
- OPPT New Chemicals Division decision logic
  - Basic program
  - In-depth program

Federal Regulatory Oversight: NIOSH

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- Robust research program
- Extensive education and outreach
- NIOSH Information Exchange: Approaches to Safe Nanotechnology (October 2005)

http://www.cdc.gov/niosh/topics/nanotech/nano_exchange.html)

Federal Regulatory Oversight: FDA

- FDA regulates a range of products – goods, cosmetics, drugs, devices and veterinary products – some of which may contain nanoscale materials (http://www.fda.gov/nanotechnology/)
- FDA formed a Nanotechnology Interest Group (NTIG)
  - Membership includes representatives from all the Centers
  - NTIG meets quarterly
- Public stakeholder meeting planned for October 2006

NGO Initiatives (cont'd)

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- NGO regulatory initiatives
  - ED Toxic Substances Control Act (TSCA) regulatory advocacy
  - Friends of the Earth, et.al. FDA Petition (http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf)
  - Action Group on Erosion, Technology and Concentration (ETC) Advocacy

Industry Initiatives

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- **Focus on product stewardship, research and advocacy**
  - ACC Nanotechnology Panel – Joint Statement of Principles with ED
  - International Council of Chemical Associations (ICCA) Nanomaterials Task Force
  - U.S. Council for International Business (USCIB)
  - Business Industry Advisory Committee to the Organization for Economic Cooperation and Development (OECD) (BIAC)
  - European Chemical Industry Council (CEFIC) Nanotechnology Center of Excellence

Industry Initiatives (cont'd)

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- **ACC Nanotechnology Panel Mission**
  - Coordinating and advocating information needed to assess and manage the health and environmental risks associated with nanoscale materials
  - Advocating for research on nanomaterials/products that facilitates understanding of the Health, Environmental and Safety (HES) aspects of nanomaterials
  - Promoting the development of nanotechnology products in conjunction with Global Product Stewardship and Sustainable Development principles

Industry Initiatives (cont'd)

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- **ACC Nanotechnology Panel Mission**
  - Advocating the use of existing regulatory framework for the responsible development and management of nanoscale materials
  - Supporting the development of appropriate, science-based regulations and harmonized international standards for nanotechnology
  - Engaging and collaborating with other stakeholders to develop and maintain public awareness and acceptance of nanotechnology

Industry Initiatives (cont'd)

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- **ACC Nanotechnology Panel Mission**
  - The Panel will conduct activities in a transparent manner and maintain open dialogue with stakeholders to achieve its missions

- **Other industry consortia – U.S. Chamber of Commerce, CropLife America, ORC Worldwide, among others**

Nanotechnology Consortium

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- Nanoparticle EHS Consortium
  - 14 member companies
  - Driven by need for answers
- Deliverables
  - Well-characterized aerosol
  - Develop portable prototype air sampling instrument for daily monitoring in R&D, manufacturing and product use settings
  - Measure filtration/barrier efficiency of filter media to specific engineered nanoparticles

Nanotechnology: Attention Areas

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- Standards
- Measurement
- Best Practices
- Testing
- Controls
- Characterization

Nanotechnology

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- Historically: Government-based regulatory (Command and Control)

- New / Different Technology

Nanotechnology: New Approach

- Public confidence
- Competitive pressures
- Difficulties in enacting new legislation
- Complex issues
- Speed to market
- Resources

Nanotechnology: Today

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- Corporate Stewardship
- Sustainability
- Voluntary Programs
- Flexible and performance-based standards
- Engagement
- Transparency
- Global Harmonization

Nanotechnology: Future

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- Who knows?
- General Observations
  - Struggles
  - Greater engagement of all stakeholders
  - Industry groups / individual companies will continue to develop innovative self-governance initiatives covering all aspects of EHS/PS
  - Transparency
  - Sustainability
  - Green technology / products

Nanotechnology: Future (cont'd)

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- Responsible development of nanotechnology
  - Hard work
  - Uncomfortable at times
  - Dialogue, diligence, compromise