

NANOTECHNOLOGY: THE FUTURE OF EHS REGULATORY POLICY

Preparation for Nanotechnology Regulation

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Exciting Technological Advances

An Industrial Revolution?

- New chemical properties, new products, new issues
- New products being developed at a rapid pace

Awareness of Nanotechnology

Media attention is making the public aware of these new products

- Huge increase in reports about nanotechnology
- All media involved (newsprint, internet, TV, movies, books)
- Venture capital increasingly available to companies developing nanotechnology products

Awareness Brings Scrutiny

Safety questions are being asked

- Environmental fate effects
- Human health effects (consumer and occupational exposure)
- Governmental agencies (EPA, FDA, NIOSH)
- Environmental groups calling for moratorium on introduction of new products until testing is done

Nanotechnology: Reward versus Risk

- Chemical Industry Has the Best Safety Record Among Manufacturing Industries Yet Ranks Low In Public Opinion
- Nanotechnology Goodwill Still Very High
- Public Captivated by ‘Gee Whiz’ of Nano
- Increasing Awareness of Nano
- Public Will Expect Safe Products
- Regulatory Scrutiny to Increase
- Liability Issue Important to Insurers



Environmental Protection Agency

- Toxic Substances Control Act
 - New Substance
 - Significant New Use
 - Exemptions Available (low volume, low release and exposure, polymer, R&D, test marketing)

- FIFRA
 - Pesticides
 - Antimicrobials (Nanoscale Silver)

- Nanoscale Materials Stewardship Program



Environmental Protection Agency

EPA Guidance on Examples of Engineered Nanoscale Materials Included in the NMSP

Criteria - Purposefully Produced – Includes “bottom-up” and “top-down” techniques and one or more dimensions <100 nm

- Metals (Au, Ag)
- Metal Oxides (TiO_2 , SiO_2 , ZnO_2)
- Quantum Dots
- Nanotubes, Nanowires
- Fullerenes
- Polymeric Dendrimers
- Materials derived from natural sources and further processed to produce nanoscale-sized materials



Food and Drug Administration

What FDA Regulates

- Drugs
- Cosmetics
 - Safety
 - Labeling
- Foods
 - Packaging Safety
 - Labeling
- Medical Devices
 - Premarket Approval of New Devices
- Biologics

Other Government Agencies

OSHA

- Worker Safety

Centers for Disease Control and Prevention (CDC)

- NIOSH Field Investigations

Health and Human Services - National Toxicology Program (NTP)

- Carbon Nanotubes
- Fullerenes
- Metal Oxides
- Quantum Dots

Consumer Product Safety Commission (CPSC)

- Product Safety

States

- California Proposition 65

Cities

- Berkeley, CA & Cambridge, MA

European Union

- REACH

What Can You Do To Be Prepared?

Product Stewardship is Critical
Four-Step CARE Approach

1. Communications
2. Advocacy
3. Research
4. Education

1. Communications

- Communicate all known or suspected hazards to workers, downstream partners and consumers
- Make all actions as transparent as possible to engender trust with workers, the public and regulatory officials
- Communicate with regulatory agencies
- Proactive communications allow you to better control information about your company

2. Advocacy

- Get involved with industry groups to facilitate the sharing of information
- Collective voice can be an effective tool as a valued stakeholder
- Partnering opportunities to conduct research and share costs
- Keep informed through group activities
- No need to “go it alone”

3. Research

- Be aware of research on the safety of nanomaterials
- Make sure you have sufficient scientific data on your own nanomaterials to make reasonable risk determinations
- Transmit results of research to the appropriate authorities
- Make research results publicly available to the greatest extent possible

4. Education

- Learn about all regulations applicable to your products
- Attend workshops, conferences and meetings to keep abreast of the latest EHS advances and regulatory initiatives

Summary

1. Make Safety a High Priority
2. Be Aware of All Applicable Regulations
3. Actions Should Be Transparent to All
4. Communicate Risks
5. Advocacy

Thank You!

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