

BERGESON & CAMPBELL, P.C.



**Nanomaterials Integration into Products
Managing Potential Risks and Liabilities from Nanomaterials**

**2009 Nano Summit
Research Triangle Environmental Health Collaborative
Environmentally Responsible Development of Nanotechnology**

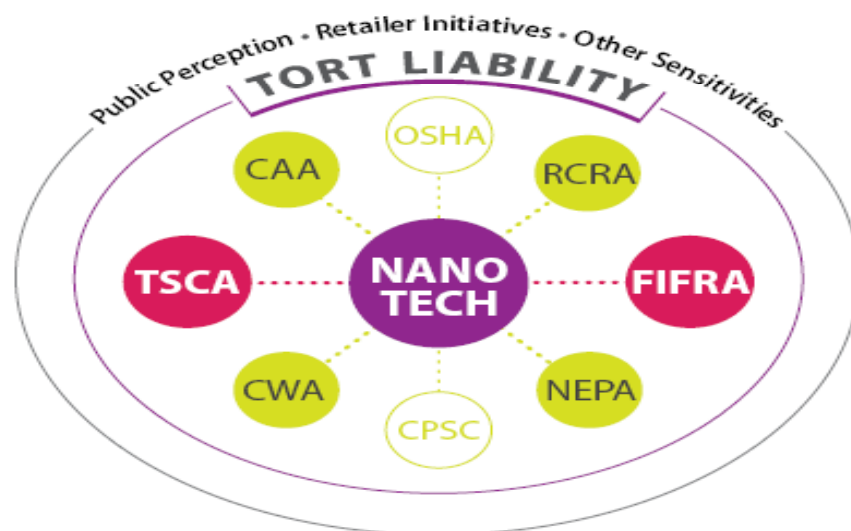
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Key Environmental Statutes

- The key federal environmental laws are broad and sufficiently robust to accommodate nanotechnology issues
- Most federal policy and regulatory activity is under the product-oriented statutes -- the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)



Toxic Substances Control Act

■ Available regulatory tools:

- Section 5 review of new chemical nanoscale materials
 - The U.S. Environmental Protection Agency (EPA) has received over 70 premanufacture notices (PMN) for nanoscale materials
- Significant new use rules (SNUR) under TSCA Section 5(a)(2)
- Early focus on carbon nanotubes (CNT)
 - CNTs are “new chemical substances”
 - EPA has acted on new chemical notices for CNTs and other nanoscale materials
 - EPA intends to regulate single- and multi-walled CNTs via SNURs but recently withdrew its July 2009 direct final SNURs on notice that adverse comments will be filed; EPA will use traditional proposed/final pathway
- EPA plans to propose a Section 8 reporting rule in 2010
- EPA is developing a Section 4 test rule for several manufactured nanomaterials
- EPA is reviewing OPPT’s “policy” on how nanomaterials are treated under TSCA

■ Potential TSCA reform

Federal Insecticide, Fungicide, and Rodenticide Act

- FIFRA Section 3's "no unreasonable adverse effects" standard requires EPA pre-registration review of pesticides with nanoscale constituents
- A current FIFRA focus is on nanosilver, added to provide an antimicrobial property to treated materials
 - EPA believes nanosilver is used in at least one currently registered pesticide and is investigating whether others, intentionally or not, may contain nanoscale constituents
 - EPA also is investigating unregistered products that claim to contain nanoscale materials and control pests
- EPA plans to convene a FIFRA Scientific Advisory Panel meeting in November to address risk assessment in the nanotechnology context -- seek guidance on what data EPA should require for nanoscale pesticide ingredients

Liability, Business, and Governance Issues

- Hazard communication obligations of employers and MSDS preparers/suppliers may become more challenging
- Product liability theories may be asserted in case of harm
 - The misnomer aside, “Magic Nano” recall is a cautionary tale
- Insurer concerns and “creative responses”
 - Exclusions, liability caps, ambiguous terminology, etc.
- Securities law reporting obligations apply despite uncertainty
 - Sarbanes-Oxley, Regulation S-K, etc.
 - Financial accounting standards (GAAP, etc.) also apply

Liability, Business, and Governance Issues (cont'd)

- Nanotechnology issues may be embraced by shareholder activists
- Acquisitions -- due diligence must be all the more diligent
- State and local governments -- proactive jurisdictions are gearing up
 - California's Department of Toxic Substance Control is gathering information via a CNT-focused data call-in
 - Nano-related initiatives (addressed to reporting, etc.) were adopted in Berkeley, CA, and Cambridge, MA
- Government-sponsored voluntary standards
 - U.S.-based (e.g., EPA's Nanoscale Materials Stewardship Program)
 - Multi-country (e.g., OECD's Working Party on Manufactured Nanomaterials and its Committee on Scientific and Technological Policy)

Liability, Business, and Governance Issues (cont'd)

- Industry standard-setting initiatives (ISO, ASTM) seek to harmonize nomenclature and measurement and address other issues
- Key private-sector stewardship initiatives
 - EDF/DuPont *Nano Risk Framework* (best management practices)
 - *Responsible NanoCode* (U.K.-created, addresses responsible conduct)
 - GoodNano Guide (addresses management in workplace settings)
- Corporate sustainability commitments may come into play

Thank you

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