

Nanotechnology: Regulatory and Litigation Update

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Today's Discussion

- We've heard:
 - What U.S. Government is doing
 - (Perhaps) what the USG should be doing
- Now:
 - What other governments are doing
 - What you should be doing

European Union's REACH Regulation

- Establishes integrated system for Registration, Evaluation and Authorization of Chemicals



REACH Regulation – Main Features

- Based on precautionary principle
- Requires companies to assess risks arising from chemical use, and take measures to manage risk
- Applies to manufacturers and importers of > 1 ton of chemical/year



REACH – Main Features (continued)

- Establishes central database
- Substances of high concern to require European Commission authorization
- Requires collection and sharing of data throughout supply chains
- “No data: no market.”
- 30,000 chemicals to be registered over first 11 years

REACH - Pre-registration

- Pre-register substances already marketed, made or imported into EU
- June 1, 2008 to December 1, 2008



REACH and Nanomaterials

- REACH: Over 800 pages; no reference to “nano”
- European Commission in June 2008: Current EU legislation, including REACH “covers to a large extent risks in relation to nanomaterials”

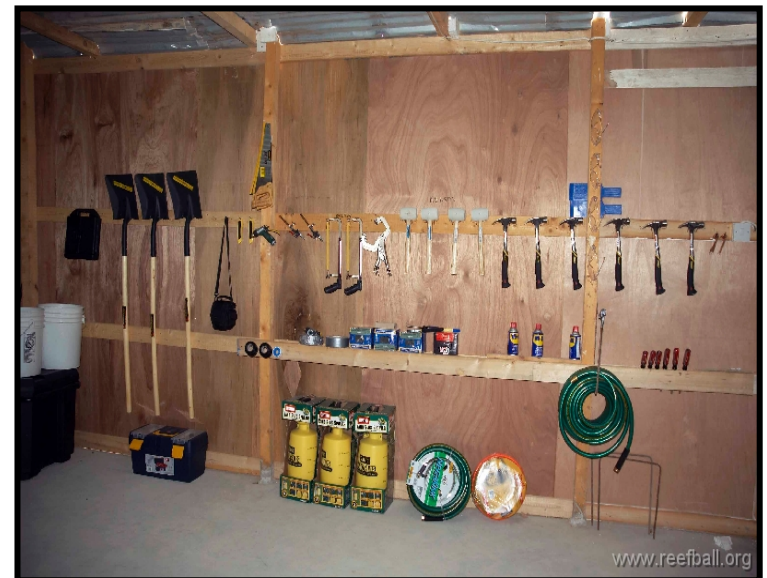
REACH and Nanomaterials

- Registration is volume-based
 - Above one ton per year, registration dossier
 - Above 10 tons per year, chemical safety report
- Existing substance on market as a “bulk substance” introduced in a nanomaterial form, update registration dossier (e.g., specific properties, additional risk management measures, etc.)
- Additional testing or information may be required

REACH and Nanomaterials

- European Commission: But current legislation may have to be modified as new information on nanotechnology becomes available
- European Commission to monitor nanomaterials under REACH and may modify the amount of a substance that triggers registration or the information requirements

Where Does That Leave Us?



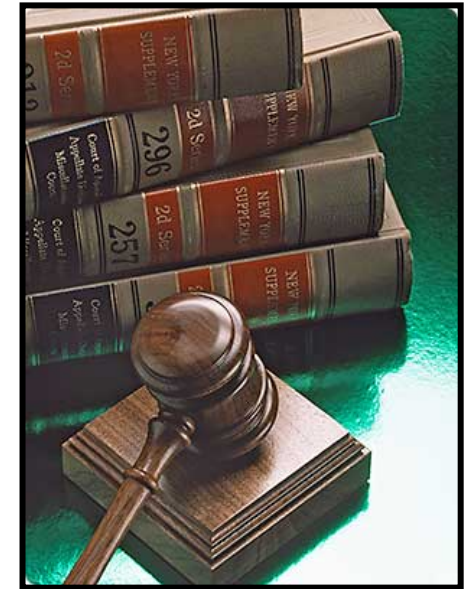
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Potential Legal Issues

- Include:
 - Intellectual property concerns
 - Product liability exposure
 - Interpretation of additional and evolving regulation
 - Substance ban or restriction



What Should You Be Doing?

- Given greater scrutiny of chemical substances throughout the world,
- Consider potential liabilities; costs; competition; and possible market exclusion for certain substances and products.



Strategic Compliance

- Position your company to protect your markets and products in the short- and long-term
- Comply but be strategic (REACH example)
- Determine your legal requirements (including local ordinances) and liability exposure
- Treat nanomaterials as if hazardous
 - Seek zero emissions
 - Control airborne exposure in workplace
- Consider management across lifecycle: from conception to development, commercialization, use and disposal

Voluntary Nano Programs and Codes

- EPA's Nanoscale Materials Stewardship Program
- DuPont/Environmental Defense Fund's Nano Risk Framework
- EU Code of Conduct for Responsible Nanosciences and Nanotechnologies Research
- Royal Society Responsible NanoCode
- BASF Code of Conduct

Questions?

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