

Nanotechnology Health & Safety Forum

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Nanotechnology: The Next 10 Years: The Risk and Prospect of Litigation

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Litigation: Where are we today?

- No reported case decisions finding engineered nano-material liability for harm;
- No pending litigation alleging engineered nano-material injuries or deaths.

What is the plan?

The Plan: Preparedness

1. A Frank Dialogue about Litigation Risk;
2. Undertake Risk Management activity now;
3. Act With a Safety Consciousness and Motivation;
4. Consider Defensive Strategies now.

1. A Frank Dialogue about Litigation Risk:

- A. Any time risk to human health and environment exists: There will be litigation.....eventually.
- B. Plaintiff's Bar is already at work.
- C. Talking about Litigation Risk is not what causes Litigation; Not talking about it leaves you less prepared for any Litigation.
- D. Set the dialogue, or someone else may set it for you.

Risk Management Programs: Positioning yourself: Just in Case.

1. Due Diligence on the health and safety risks of your product and its component parts:
2. Conduct process and product exposure and toxicity risk assessment:

Risk Management Programs: Positioning yourself: Just in Case. (CONT'D.)

- A. Characterization;
- B. Do your own research on safety/toxicology;
- C. If not possible, retain qualified third-party
i.e. Intertox;
- D. Follow the research of others on
safety/toxicology;
- E. Do as much as you can within your means;
- F. Document your efforts.

3. Life Cycle Analysis

- A. Test for weathering, durability, abrasion,
wear.

2. Maintain Insurance Coverage:

- A. Advise your Carrier about your Nano-business in the Application and Renewal Process.
- B. Follow insurance industry's on-going risk assessment of Nanotechnology industry and products.

Monitor and Participate in the Regulatory Process:

1. Watch regulatory efforts in the U.S., Canada, EU and Asia: A dynamic process.
2. Avail yourself of any opportunity for public commentary on Regulatory Affairs and Rule-Making.
3. Consider Voluntary Participation in pilot programs: i.e. EPA Stewardship Program.
4. Participate in Standards Creating Process: i.e. ISO/ANSI, ASTM, etc.
5. Regulations and Industry Standards may become basis for future Litigation.

The Plaintiffs' Arsenal:

1. A Host of Potential Attacks.

A. Negligent Design, Manufacture, and Failure to Warn claims;

B. Strict Liability Claims for Defective Products;

C. Express and Implied in Law Warranty Claims;

D. Statutory, Regulatory and Standard's based claims;

The Plaintiffs' Arsenal: (cont'd.)

- E. Consumer Protection Law claims (Private Right of Action and Enforcement by the Government);
- F. Mass Tort and Toxic Tort Law claims: (Environmental, End-User Consumer, Work-place Exposure, etc);
- G. Class Action Litigation;
- H. Medical Monitoring Claims.

The Defense Shall Prove:

1. Product Safety Programs: A documented proactive, defensible, responsible and reasonable approach by Manufacturers, Distributors; Importers, Retailers to safe Design and Manufacture;
2. Sound Scientific Research on Product Safety, Toxicology, and Causal Relationship between Exposure and Alleged Harm or Hazard;

The Defense Shall Prove: (cont'd)

3. Daubert: The Court's Gatekeeping function: Scrutiny of the Plaintiff's claims and the Plaintiff's Expert's Opinions And Proposed Testimony;
4. Defense Experts: We must have the better science, technology and methodology on our side;
5. Warnings and Instructions: When Safe Design and Manufacture Cannot Eliminate Foreseeable Risks: We should **WARN.**

Preparedness is the touchstone for the future

- Start the Dialogue now, waiting can be costly in many ways.
- Manage Your Risk today.
- Make Ready to Shield This Important Industry for the Sake of its Future.

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