“Soft Law” Governance for Nanotechnology: Liability and Insurance Implications

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Overview

- Traditional regulatory approaches for nanotechnology unlikely to be effective in near term
- Reliance on “soft law” risk management approaches
  - Problem: lackluster industry participation
- Question: Can (i) liability risk prevention and (ii) insurance requirements push companies to greater participation in soft law risk management approaches
Impediments to Traditional Regulation of Nanotechnology

- Lack of legally and scientifically valid definition of nanotechnology
- Risk uncertainty
- Lack of established methods, test procedures, sampling protocols
- Difficulty in meeting statutory triggers
- Rapid technology change ("moving target")
- Risks vs. benefits
- Regulatory gridlock
Comprehensive Regulation Unlikely Anytime Soon

- Traditional regulatory responses unlikely to provide satisfactory oversight of nanotechnology in near-to mid-term
  - prevention of risk/harm
  - public confidence

- Sui generis regulation of nanotechnology may not be appropriate at this time
  - tilt scales against all things nano
"If you increase the magnification another million times you can see the safety regulations."
“Soft Law” and Nanotech

- Substantive obligations and requirements created by instruments that are not directly legally enforceable

- “in the absence of detailed research into the risks associated with many nanomaterials, we believe that voluntary approaches need to be developed and implemented to complement existing regulations and to provide guidance on prudent measures to control risk”

- “[I]t appears on balance that the current state of the science supports non-regulatory ad hoc approaches that are responsive to specific circumstances”
Advantages of Soft Law

- Voluntary; cooperative
- Reflexive
- Can be adopted or revised relatively quickly
- Many different approaches can be tried simultaneously
- Can be gradually “hardened” into more formal regulatory oversight
Model: Incremental, Cooperative, Reflexive Oversight

GRADUATED REGULATORY PYRAMID

- Immediate
  - Information Gathering/Dissemination
- Short Term
  - Self-Regulation
  - Multi Stakeholder Norms
- Medium Term
  - Enforced Self-Regulation
- Long Term
  - Hard Law/Legislation
Example of “Soft Law” Nanotechnology Risk Management Programs

- Dupont/EDF Nano Risk Framework
- Standards bodies – e.g., ISO
- Responsible NanoCode
- EU Code of Conduct for Responsible Nanotechnology Research
- CENARIOS®
- NIOSH Guidances
- Responsible Care program
- GoodNanoGuide (ICON)
- Other company & industry standards
The Nanotechnology Governance Triangle

NANO Risk Framework

Environmental Defense - DuPont
Nano Partnership

June 2007
EDF – DuPont Nano Risk Framework

Describe Material & Application

Profile Lifecycle(s)
- Properties
- Hazards
- Exposure

Evaluate Risks

Assess Risk Mgmt

Decide, Document & Act

Review & Adapt

Assess, prioritize & generate data

Some Anecdotal Responses to Nano Risk Framework

- “Insurers ... would do well to seek evidence of whether projects they are covering have followed this framework.” - Lloyd’s

- “Arguably sets a “Standard of Care” for the Nanotechnology Industry and beyond” - General Electric

From joint Dupont/EDF training session
Standard-Setting Organizations

- **International Organization for Standardization (ISO)**
  - Technical Committee 229 -- Four Nanotechnology Subcommittees: Terminology and Nomenclature; Measurement and Characterization; Health, Safety, and Environmental Aspects; and Material Specifications

- **ASTM**
  - Technical Committee E56 on Nanotechnology -- Addresses issues on standards and prepares guidance materials on nanotechnology and nanomaterials
ISO Adopts Nano-Risk Framework in May 2011

ISO/TR 13121:2011

Nanotechnologies -- Nanomaterial risk evaluation

Abstract

ISO/TR 13121:2011 describes a process for identifying, evaluating, addressing, making decisions about, and communicating the potential risks of developing and using manufactured nanomaterials, in order to protect the health and safety of the public, consumers, workers and the environment.

ISO/TR 13121:2011 offers guidance on the information needed to make sound risk evaluations and risk management decisions, as well as how to manage in the face of incomplete or uncertain information by using reasonable assumptions and appropriate risk management practices. Further, ISO/TR 13121:2011 includes methods to update assumptions, decisions, and practices as new information becomes available, and on how to communicate information and decisions to stakeholders.

ISO/TR 13121:2011 suggests methods organizations can use to be transparent and accountable in how they manage nanomaterials. It describes a process of organizing, documenting, and communicating what information organizations have about nanomaterials.
Soft Law Approaches: Lack of Industry Incentives

- In current atmosphere, incentives for identifying your products as nano mostly negative
- Few positive incentives and many negative incentives to participate in voluntary programs
- Industry participation in Nano Risk Framework and other soft law programs has been tepid at best

“To date ... soft law mechanisms for nanotechnology have had a mixed record. Some remain focused on preliminary technical matters; some have not developed fully; some have promulgated broad principles or practices whose depth of commitment is questionable; few actively promote effective implementation; and none engage in monitoring or provide strong incentives for adoption and compliance. Currently, then, few of these mechanisms seem well positioned to play significant, beneficial roles in ensuring the safe development of nanotechnology.”

“Voluntary measures ... can play ... an important, constructive role in the present state of nanoregulation, to build a knowledge base to support policy and regulatory decisions, and on nanotechnologies oversight. Therefore they should be retained while finding ways to overcome their limitations and encourage people to use them, without changing their nature.”
Liability Prevention Can Be A Driver of Soft Law Adoption
“Experience ... teaches that when there are concerns about possible health and safety hazards, trial lawyers are never far behind. The question is not so much if, but when, nanotort claims and litigation will arise.” Richard G. Morgan & Ronald C. Wernette, *Reducing the Risk of Nanotechnology Personal Injury Litigation*, ABA Products, General Liability and Consumer Law Committee News, Summer 2010, at 1, 19.
Lawyers are Hungry for the Next Mass Tort Opportunity
Pro-Litigant Features of U.S. Liability System

- Extensive use of juries
- Class actions
- Strict liability
- Contingent fees
- Punitive damages
- Novel latent risk claims
  - Increased risk, fear of cancer, medical monitoring
Challenges for Nanotechnology Personal Injury Lawsuits

- Knowledgeable plaintiffs attorney
- Latency
- Proving exposure
- Identifying defendant
- Proving causation
- State of the art defense
- Daubert
Litigation Implications of Participation in Soft Law Programs

- “Evolving private sector codes of conduct are becoming the *de facto* legal standard against which to measure corporate behavior”
  - Lyn Bergeson, Bergeson & Campbell PC

- “[I]ndustry standards and best practices are the minimum standard of care to which [an] organization is likely to be held.”
  - Edward Grandy et al. (2012)
Participation as Shield

- Compliance with standards rarely a complete shield against liability
- But can demonstrate acted at or above industry standard of care:
  - private standards and programs can “suggest[] a standard of care as a yardstick in emerging areas where the legal standard is not as clear against which the conduct of organizations can be measured.” Bell & Marrapese (2011)
- Allows defendant to tell a persuasive story to jury about corporate responsibility
- Participation can also help protect against punitive damages
Non-Participation as Sword

- Defendant’s failure to meet private standard arguably shows lack of due care
  - “Although the ASTM standards are non-binding and a reasonable jury could discredit their persuasiveness, for summary judgment purposes, the standards as applied to the stairs satisfy Plaintiff’s burden of presenting evidence of defect. By failing to comply with the ASTM standards, a jury could conclude that the stairs were not reasonably fit, suitable and safe for their intended purpose.” Donlon v. Gluck Group, LLC, 2011 WL 6020574, *4 (D.N.J., Dec. 2, 2011).
Limitations of Standards in Defining Standard of Care

- Standards adopted by recognized standard-setting organizations (ISO, ANSI, ASTM) likely have greater weight with courts than ad hoc nano-specific standards.
- Standards that have received “industry wide” recognition entitled to greater support.
- Standards must remain up-to-date.
Insurers as Drivers of Nano Soft Law Risk Management Programs
Insurers’ Concerns About Nanotechnology

“Nanotechnology, as an emerging risk, challenges the insurance industry because of the high level of uncertainty in terms of potential nanotoxicity or nanopollution, the ubiquitous presence of nano-products in the near future (across industry sectors, companies and countries) and the possibility of long latent, unforeseen claims.”

Insurers Role as Surrogate Regulators

- Liability insurance providers are increasingly assuming a “quasi-regulatory” role in requiring their clients to engage in sound risk management practices as a condition for coverage.

- “In the absence of health and safety standards, the insurance industry can play a balancing role. Insurance and risk management are essential enablers for the successful commercialization of nanotechnology. We don’t want to hamper development, but rather, bring the consideration of health and safety to the table.” A. Rsiwadkar, Zarich Services Corp.
Some Insurer Initiatives with Nanotechnology

- Anecdotal reports of insurers recommending Nano Risk Framework or equivalent
- In 2008, one insurance company excluded nanomaterials from its comprehensive general liability (CGL) policies
- Lexington Insurance Company offered LexNanoShield policy to provide nano risk management services
Some Limitations on Role of Insurer in Nano Risk Management

- Unclear what nano risks excluded by general pollution exclusion clauses
- Uncertainty about appropriate risk management practices
- Enforcement/compliance monitoring by insurance companies?
- Small companies may not be able to undertake Nano Risk Framework obligations
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