

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

Nov. 4, 2013

Gary E. Marchant, Ph.D., J.D.

[gary.marchant@asu.edu](mailto:gary.marchant@asu.edu)

CENTER FOR  
Law, Science & Innovation

**ASU** SANDRA DAY O'CONNOR  
COLLEGE of LAW  
ARIZONA STATE UNIVERSITY

Innovating law, policy and ethics for science & technology

# 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

© Original Artist  
Reproduction rights obtainable from  
[www.CartoonStock.com](http://www.CartoonStock.com)



"If you increase the magnification another million times you can see the safety regulations."

# “Soft Law” and Nanotech

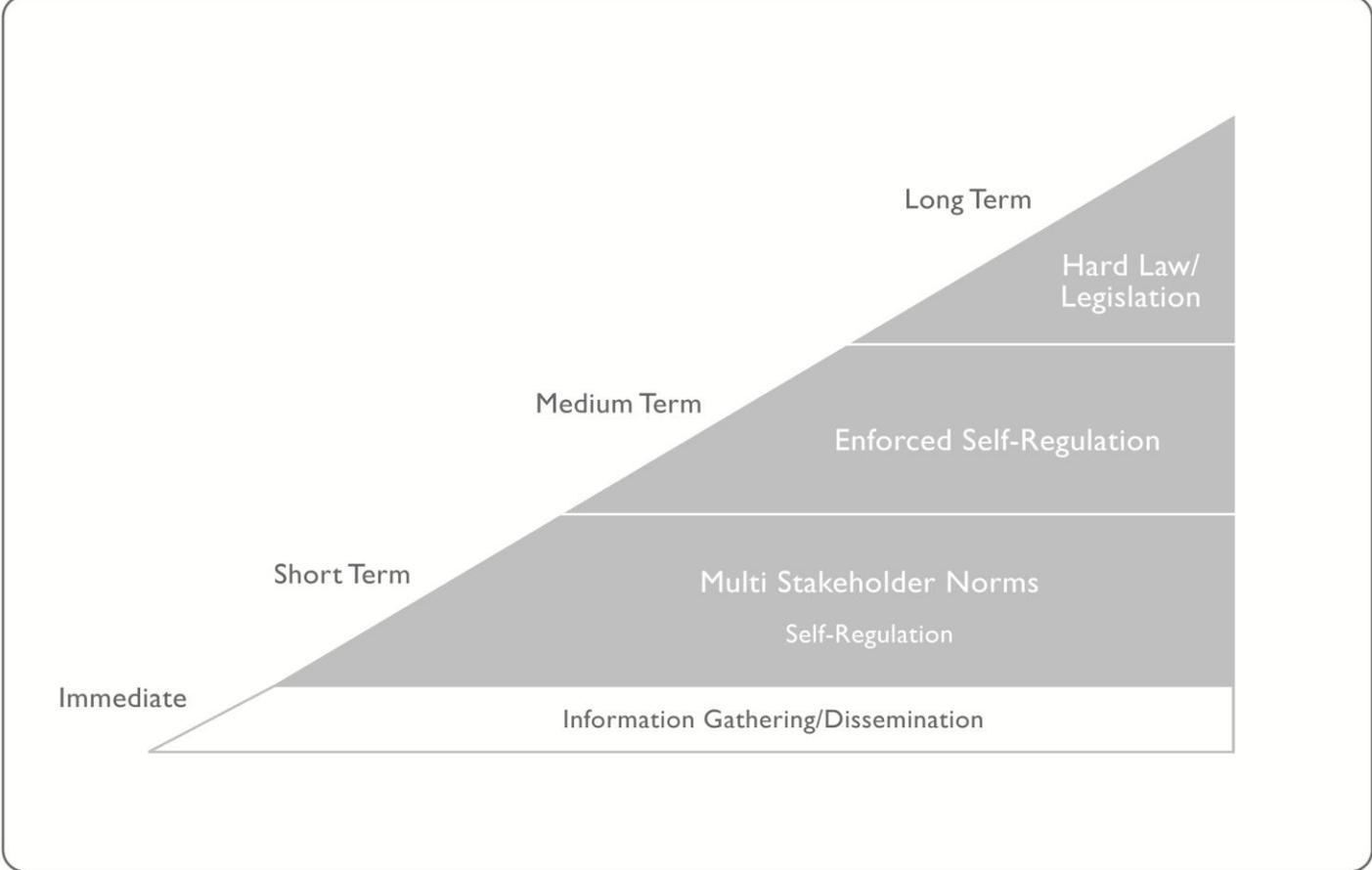
- Substantive obligations and requirements created by instruments that are not directly legally enforceable
- “in the absence of detailed research into the risks associated with many nanomaterials, we believe that voluntary approaches need to be developed and implemented to complement existing regulations and to provide guidance on prudent measures to control risk”
  - Vladimir Murashov & John Howard, *Nature Nano* (2009)
- “[I]t appears on balance that the current state of the science supports non-regulatory ad hoc approaches that are responsive to specific circumstances”
  - Andrew D. Maynard, *J. Law Med Ethics* (2009)

# 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

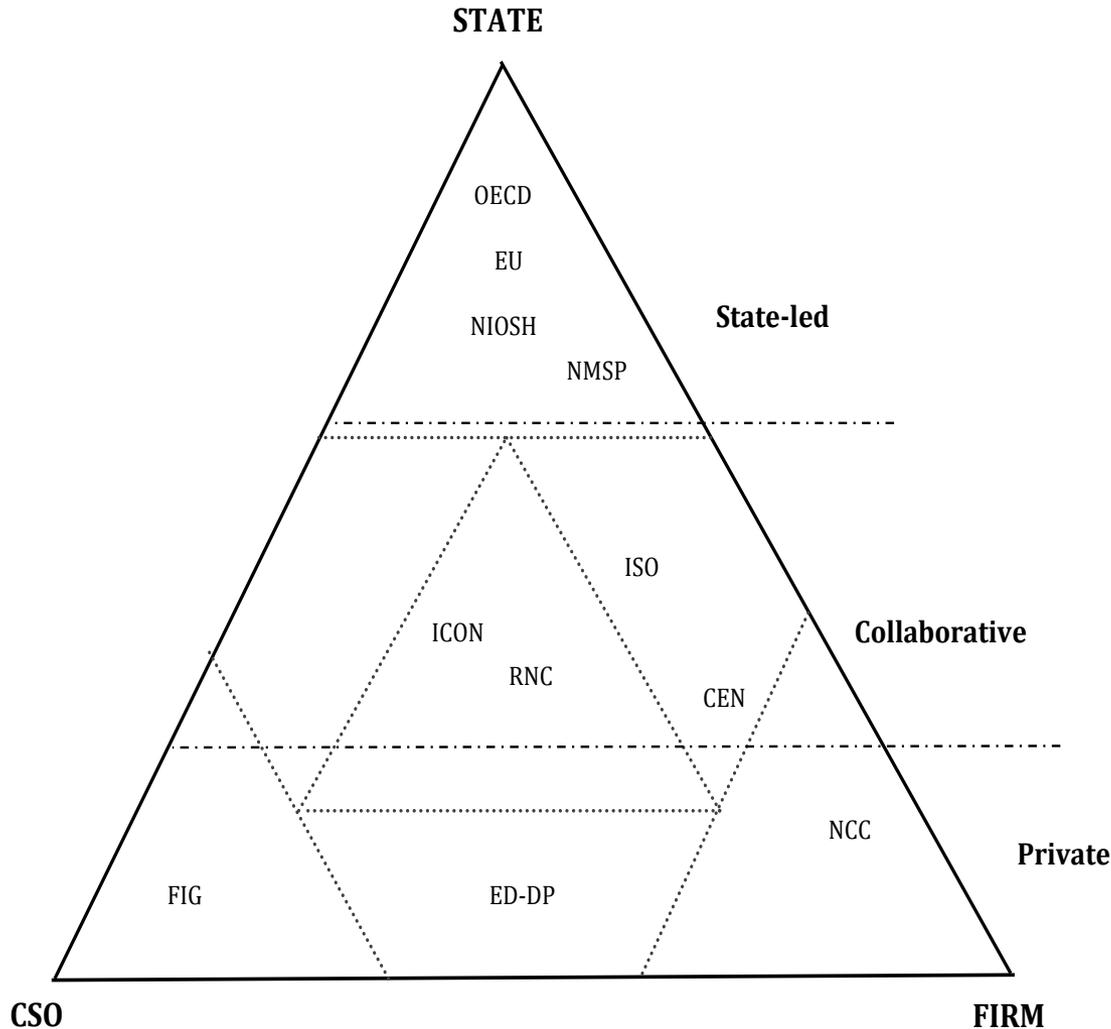
## GRADUATED REGULATORY PYRAMID



# 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



**CEN** CENARIOS  
certification program  
**ED-DP** ED-DuPont  
NanoRisk Framework  
**EU** EU Code of  
Conduct  
**FIG** Foresight  
Institute Guidelines  
**ICON** ICON Good  
Nano Guide  
**ISO** ISO Standards  
**NCC** NanoSafety  
Consortium for  
Carbon  
**NIOSH** NIOSH  
Guidelines  
**NMSP** EPA  
Nanoscale Materials  
Stewardship Program  
**OECD** OECD  
Working Party  
**RNC** Responsible  
NanoCode

# NANO Risk Framework

Environmental Defense - DuPont  
Nano Partnership

June 2007



*The miracles of science™*

e

ENVIRONMENTAL DEFENSE  
finding the ways that work

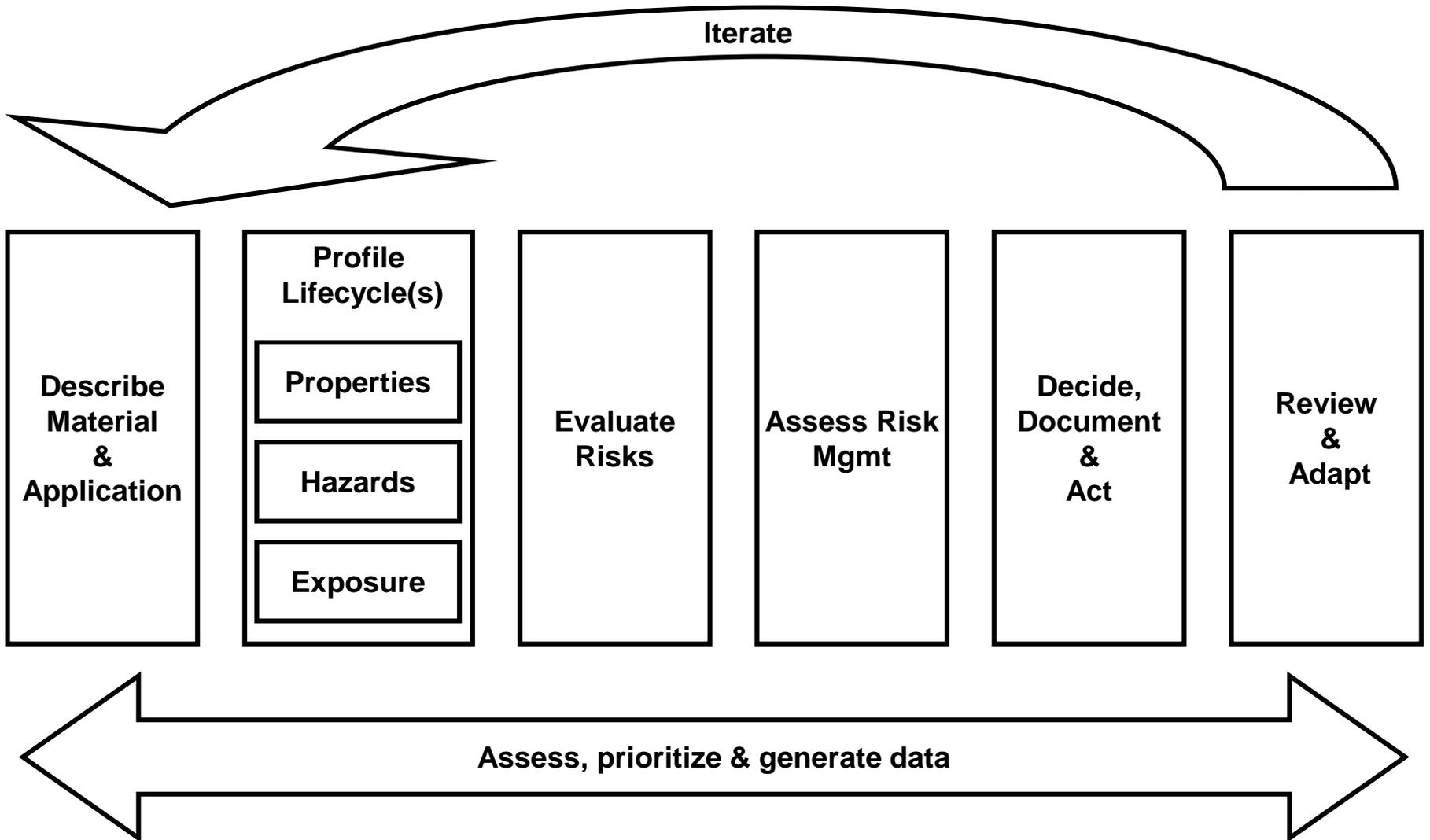
e

ENVIRONMENTAL DEFENSE  
finding the ways that work



*The miracles of science™*

# EDF – DuPont Nano Risk Framework



# 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

# Nano Soft Law Assessment: Abbott et al (2012)

- “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.”

# Nano Soft Law Assessment: ObservatoryNANO (2012)

- “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

## 1. **LAW:** What's the next big thing in nanotech? Litigation (08/14/2008)

Sara Goodman, Greenwire reporter

Nanotechnology – the science of manipulating matter at the nanoscale, down to 1/100,000 the width of a human hair, to create new and unique materials and products – holds great promise for revolutions in medicine, energy and agriculture.

“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. "
- Swiss Re, Nanotechnology: Small Matter, Many Unknowns, Few Conclusions (2004)

# 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

# Acknowledgement

- Funding for work on nano soft law approaches provided by the U.S. Department of Energy, Office of Science (BER), Grant No. DE-FG02-07ER64475
- Manuscript currently under review at *Journal of Risk Research* (available by request from gary.marchant@asu.edu)