

*Nanotechnology: Regulatory
and Litigation Update*

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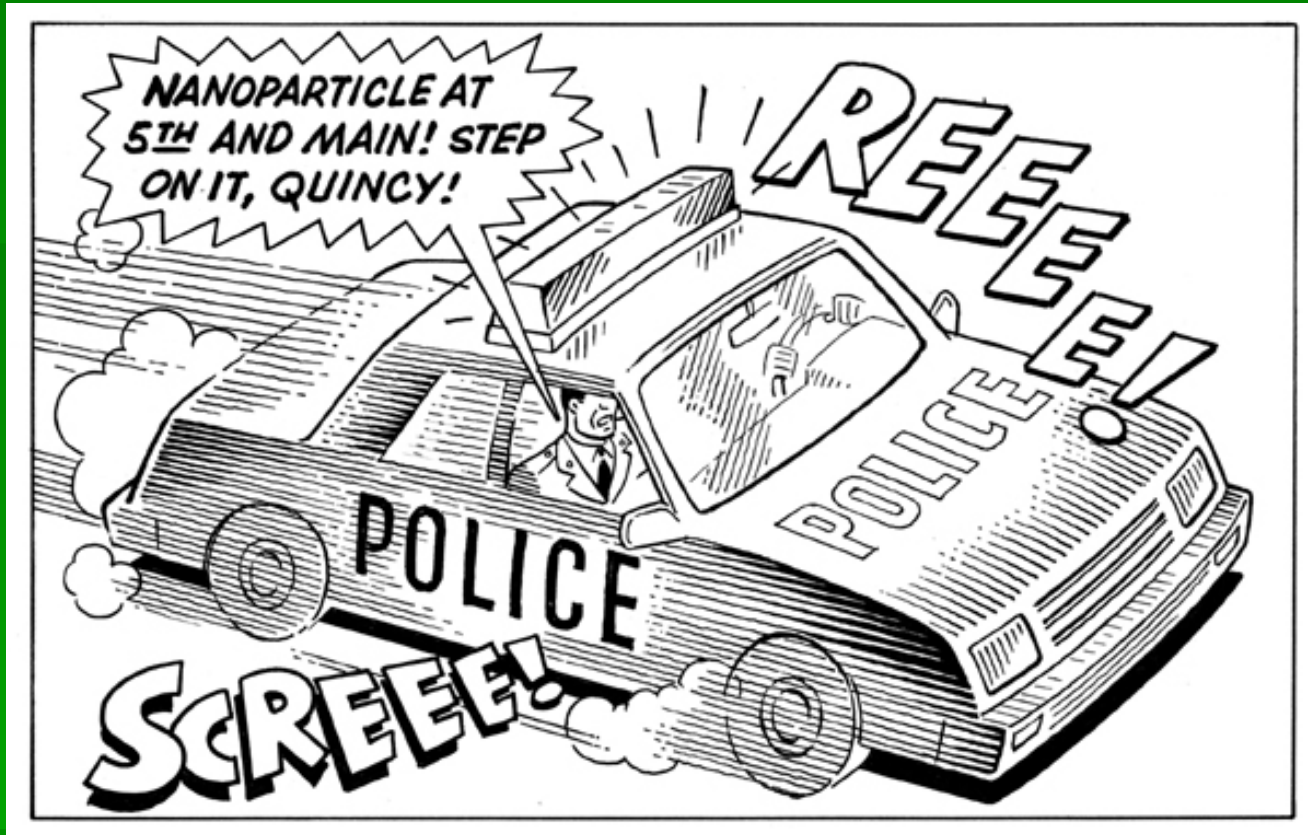
*The International Center for
Technology Assessment*

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Environmental Law Institute
Washington, DC

- CTA is a Washington, D.C.-based non-profit, non-partisan organization committed to providing the public with full assessments and analyses of technological impacts on society. CTA explores the environmental, human health, economic, ethical, social and political impacts that can result from the applications of technology or technological systems.

A Snapshot of Nanotechnology Oversight



“Federal and state regulators . . . have so far been happy to sponsor meetings and studies that call for regulation **but notably reluctant to engage in any.** A **very small fraction** of the billions of dollars being invested in nanotechnology research is being **used to ferret out potential risks.**”

- Barnaby Feder, *Teeny-Weeny Rules for Itty-Bitty Atom Clusters*, New York Times, January 16, 2007



Toxic Substances Control Act (TSCA)

Nanoscale Materials Stewardship Program

- Summer 2005: NMSP proposed
 - voluntary submission of basic materials data (e.g., characterization, hazard, use/exposure, and risk management procedures)
 - coalition of NGOs: “inadequate and inappropriate,” no incentive for participation, no mandatory regulation component, will delay needed mandatory regulation and forestall public involvement
- January 2008: NMSP starts after +2 years delay
 - Essentially same program, critiques unaddressed
 - EPA estimated 240 companies to participate



Toxic Substances Control Act (TSCA)

Nanoscale Materials Stewardship Program

(continued)

- Summer 2008: NMSP concludes
 - Only 4 companies in “basic” as of July 14
 - None in “in-depth”
 - Result: still lack even basic data on scope of/type of nano-related activities and safety, despite explosion of products (3-4 new products each week)
 - Failure foreseeable (see UK voluntary nano program '06-08, Danish program)



Toxic Substances Control Act (TSCA) *a viable regulatory vehicle for nano?*

EPA TSCA Inventory Status of Nanoscale Substances – General Approach (August 07-Jan 08)

- concludes vast majority of nanomaterials are “existing” not “new” (i.e., size doesn’t matter)
 - NGOs, NIOSH: decision contrary to scientific reality, commercial reality and bad policy
 - Eliminates only chance for even limited pre-market review
 - Nothing about new use rules (TSCA Section 5 SNURs) or reporting requirements (TSCA Section 8)
 - Davies: policy makes TSCA a “dead letter” with respect to nanotech



Toxic Substances Control Act (TSCA) *a viable regulatory vehicle for nano?* *(continued)*

- TSCA suffers from major shortcomings generally and when applied to nanomaterials
 - Weak regulatory instrument: assumes no info=no risk; data burden on agency not manufacturer (compare REACH)
 - Very high bar for agency rule-making (i.e., Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).
 - Exemption gaps inappropriate for nano (i.e., low volume)

Hmm... any other
oversight means for
commercialized
nanomaterials??

Nano-silver: the fastest growing sector of nanomaterial product commercialization

- Food storage, children's toys, washing machines, refrigerator linings, shoe linings, air filters, paint, coatings, cleaning sprays and wipes, cutlery, clothing, hair products, computer accessories and wide range of other products
- Inserted for their nano-enhanced “germ-killing” anti-microbial properties
- However same properties can harm aquatic organisms, beneficial microorganisms and ecosystems once the product enters the natural environment through use or disposal





Nano-silver EPA procedural history

- Feb 2006: Public utilities (NACWA) request EPA to regulate certain “silver ion” consumer products as pesticides under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Nov 2006: EPA responds-
 - Nano-silver products to be classified as pesticides if make germ-killing claims;
 - proposed rule forthcoming in “next couple of months”; “first federal restriction to focus largely on nanotechnology”; (Wash Post. 11/23/06)
- Sept 2007: EPA Guidance on “ion-generating” machines
 - Limited to washers, allowed to remain on market
 - Disavows that this is “an action to regulate nanotechnology”
 - No opportunity for public comment on other products, broader regulation



Nano-silver FIFRA Petition

- May 2008: CTA and coalition of consumer, health, and environmental groups file legal petition calling on EPA to regulate nano-silver as a pesticide.
 - +270 nano-silver consumer products found
 - Nano-silver meets the FIFRA definition of “pesticide” b/c highly efficient antimicrobial agent and is intended for that purpose
 - (See also Consent Agreement b/w EPA and ATEN Tech (Feb 2008))
 - Pesticides require premarket review of potential harmful effects



Nano-silver Petition (continued)

Petition calls on EPA to, *inter alia*:

- Regulate nano-silver products as pesticides
- Classify as “new” pesticides
- Assess human health and environmental risks of nano-silver
 - *FIFRA, FQPA, ESA, NEPA*
- Prohibit sale of illegal nano-silver pesticides until/unless they register and are approved
- Require/amend regulations: nano-specific ingredient and warning labeling, data, and testing

Conclusion: what is needed

A Precautionary Foundation

Mandatory Nano-specific Regulations

Health and Safety of the Public and Workers

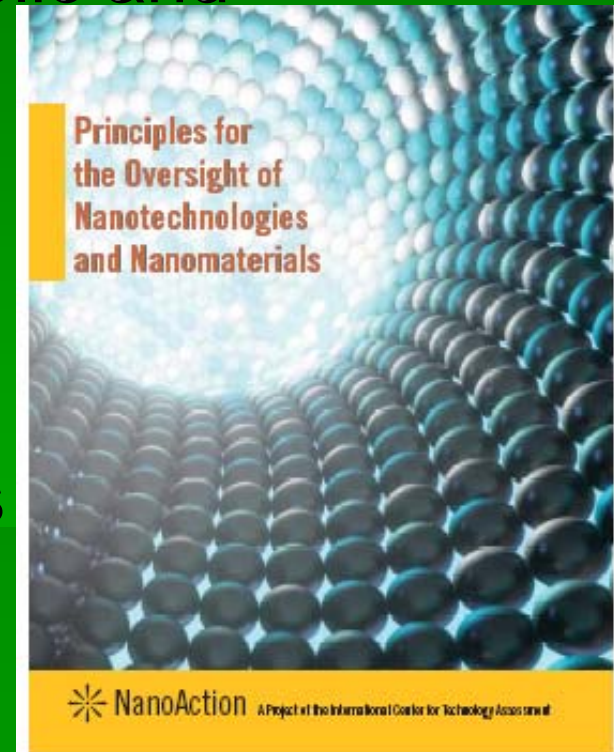
Environmental Protection

Transparency

Public Participation

Inclusion of Broader Impacts

Manufacturer Liability



Publicly released 7/31/07; available at www.icta.org; already endorsed by more than 70 organizations spanning six continents.

For More Information

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