Statement of Findings: Taking Action on Nanotech Environmental, Health, and Safety Risks

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This is a **statement of findings** from the May 2006 Lux Research report "Taking Action on Nanotech Environmental, Health, and Safety Risks." The full 39-page report is available to clients of Lux Research's Nanotechnology Strategies advisory service. For information on how to become a client, contact Rob Burns at rob.burns@luxresearchinc.com.

One of the biggest challenges facing firms commercializing nanotechnology innovations today is managing environmental, health, and safety (EHS) risks. Worries about nanomaterials EHS have grown in prominence over the last year; to deal with them, companies must confront three challenges (see Figure 1):

- **Real risks are uncertain.** Companies need to ensure nanotech applications won't harm people or the environment, but addressing real EHS risks can be a challenge for nanomaterials due to a lack of data, the complexity of the materials, measurement difficulties, and undeveloped hazard assessment frameworks. Lux Research analyzed peer-reviewed journal articles from Science Citation Index searches, the database maintained by the International Council on Nanotechnology (ICON), and review articles; we found just 316 focused on hazard or exposure of engineered nanomaterials. This literature is growing but still not sufficient for firms to make firm decisions about real risks.

- **Perceptual risks aren't determined.** Firms also face the risk that the public will reject product made using nanotech, irrespective of the actual danger. Currently, the public remains positive on nanotech despite little knowledge – one study found awareness of nanotech at 35% and 42% among Canadian and U.S. residents, with optimism at 87% and 86% respectively. NGOs are beginning to take up the issue, but have viewpoints ranging from those calling for a moratorium, like the ETC Group, to those working with industry, as Environmental Defense has with DuPont. Press coverage has pick up on risks, but two to three times as many stories focus on benefits. Firms worry about perceptual risks but have found no answer other than keeping their nanotech efforts quiet – many cited a policy of avoiding risk by simply not labeling products as "nano."

- **Regulations haven't been set.** EHS regulations will govern nanomaterials in a variety of applications, but exactly how the relevant laws will be applied isn't settled. In the U.S., the EPA is preparing a voluntary Stewardship Program to solicit data on nanomaterials, but hasn't determined whether or when nanomaterials will be considered new substances under statutes like the Toxic Substances Control Act (TSCA). Regulations at other agencies around the world are similarly uncertain. Corporations are frustrated by their inability to plan ahead, while start-ups fret about over-regulation.

Fig. 1: Companies Must Consider Three Categories of Nanotechnology EHS Issues

Real risks

Nanomaterials might have negative effects on people or the environment

Rat exposed to cobalt nanoparticles on the left side, bulk cobalt on the right side

Best case: Nanomaterials prove to be more dangerous than ordinary substances in only a handful of cases

Worst case: Studies show that many nanomaterials have elevated hazard and are more difficult to control

Perceptual risks

Nanotechnology might come to be seen as unsafe – irrespective of actual harm

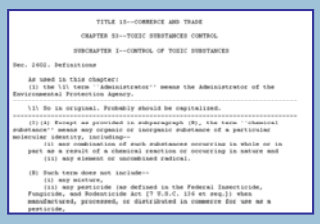
Protest of the use of Nano-Tex fabric treatment outside an Eddie Bauer store

Best case: Consumers appreciate the benefits nanomaterials can offer and embrace the technology

Worst case: Nanotech comes to be seen as synonymous with danger and consumers are reluctant to accept it

Regulations

Regulations might – rightly or wrongly – slow or block commercialization



TITLE 15--COMMERCE AND TRADE

CHAPTER 53--TOXIC SUBSTANCES CONTROL

SUBCHAPTER I--CONTROL OF TOXIC SUBSTANCES

Sec. 2602. Definitions

As used in this chapter:

(1) the \1\ term ''Administrator'' means the Administrator of the Environmental Protection Agency.

\1\ So in original. Probably should be capitalized.

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(7)(A) Except as provided in subparagraph (B), the term ''chemical substance'' means any organic or inorganic substance of a particular molecular identity, including--

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and

(ii) any element or uncombined radical.

(B) Such term does not include--

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,

Text of the Environmental Protection Agency's Toxic Substances Control Act

Best case: Existing regulatory frameworks case be painlessly adapted to manage nanomaterials

Worst case: Risks drive regulators to impose stringent testing requirements on all nanomaterials

To ensure that EHS issues won't derail their nanotech efforts, firms need to fast-track a comprehensive plan to address all three aspects of the problem, including:

- **A process for dealing with real risks.** To keep themselves in the clear on real risks, firms must 1) inventory all nanomaterials used across the company, 2) map materials to applications and thus to potential exposures across the product life cycle, 3) characterize the risk of each application based on exposure and available knowledge about hazard, and 4) mitigate risk through exposure controls, additional testing, and product redesigns (see Figure 2). Three categories of nanomaterals define the categories of research needs for risk assessments on nanomaterials: Novel chemical structures like carbon nanotubes, where hazards and exposures are unknown; nanoscale particles of known materials like titanium dioxide, where data exists on the bulk material, but nanoparticles may present elevated hazard and exposure; and nanoscale assemblies of smaller molecules, such as micelles and emulsions, where new exposure routes are possible but hazards beyond those of the constituent molecules are unlikely.
- **Communicating to guard against perceptual risk.** Avoiding the topic won't protect against perceptual risks, it will exacerbate them. Instead of remaining silent, companies should share their safety studies, collaborate with trusted partners, and explain the benefits nanotech can bring. Their strategies should take into account cultural differences in various regions, varying consumer attitudes toward technology in different products and industries, and variations in the psychographic profiles of the customer base.

Fig. 2: Four-Step Process for Managing Real Risk

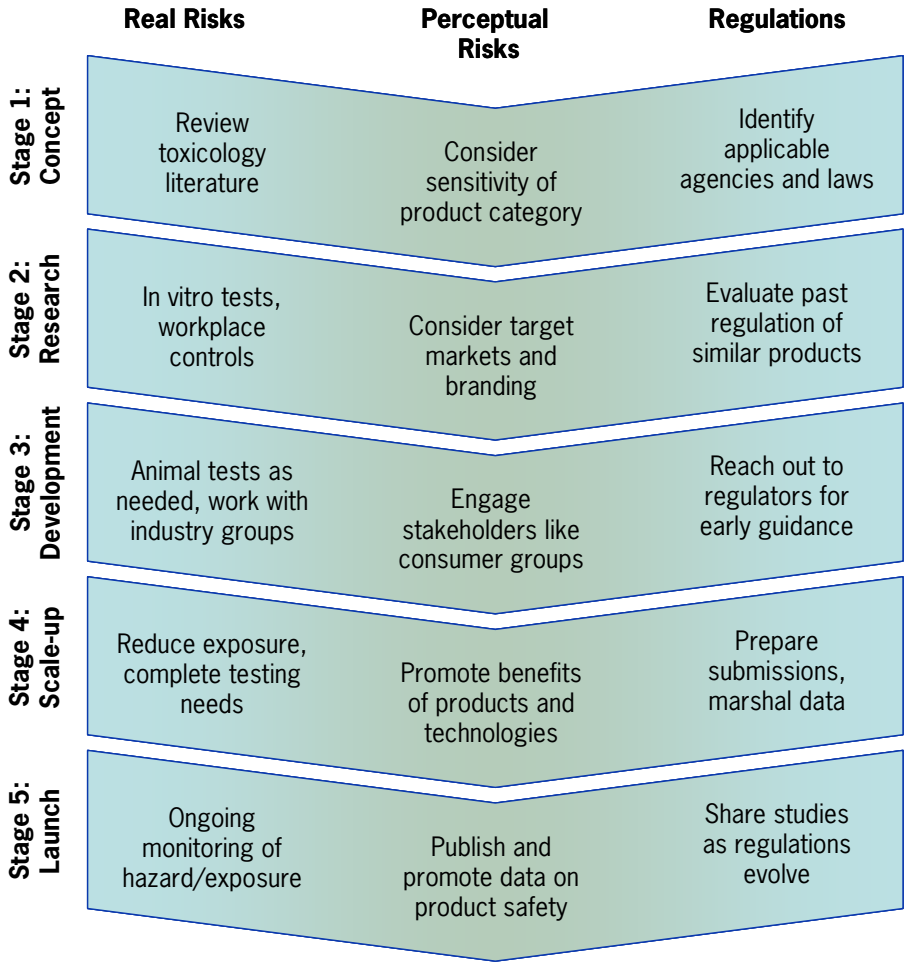
1. Nanomaterials inventory	2. Applications and exposures	3. Risk characterization	4. Risk mitigation
Purpose: Identify potential sites of nanotech EHS risk	**Purpose:** Determine who or what might be exposed	**Purpose:** Assess risk from hazard and exposure	**Purpose:** Take concrete steps to minimize risk
Objectives: • List nanomaterials being made in-house • List nanomaterials being purchased • Project additional likely nanomaterial uses	**Objectives:** • List applications each nanomaterial is used in • Identify occupational controls used in-house • Project additional likely nanomaterial uses	**Objectives:** • Project potential hazard using available data • Combine hazard and exposure to gauge risk • Identify areas where action is needed	**Objectives:** • Use appropriate controls across the lifecycle • Conduct additional toxicity tests as needed • Establish ongoing monitoring
Owner: Line of business or R&D nanotech team	**Owner:** Nanotech team jointly with EHS function	**Owner:** EHS function with nanotech team support	**Owner:** Lines of business with EHS function support

- **Solid projections of the regulatory landscape.** To best prepare for regulations, firms should understand how the U.S. Environmental Protection Agency (EPA) will adapt existing regulations to accommodate nanomaterials while recognizing that the U.S. Food and Drug Administration (FDA) will continue to make judgments on a product-by-product basis. Other U.S. regulatory bodies will be less involved, and regulations in Europe will trail those in the U.S.

The near-term steps outlined above will get firms well within the safe zone of real and perceptual risks and ensure they meet regulatory requirements. However, to balance the need for safety with profitability, firms that use nanomaterials will need to apply them with greater breadth and frequency going forward. Nanotech's unique EHS needs will drive a new product development framework, just as complex manufacturing drove the "Total Quality" movement. Companies can't afford to run extensive toxicity tests on each material their scientists consider using, but they also can't wait until just before product launch to consider EHS concerns. Instead, a staged approach to managing EHS issues should match appropriate actions to each step in the product development process (see Figure 3).

While no company wants overly burdensome regulations, smart firms recognize that a lack of regulation can also hurt commercialization by exacerbating real and perceptual risks; we believe that under-regulation is, for now, a more likely outcome than over-regulation. Start-ups and small caps which have gotten a free pass from investors on EHS to date will increasingly face tough questions about their plans for managing these issues. We recommend that companies unite to meet new testing needs for nanomaterials, as Bayer, Arkema, and Nanocyl have done for carbon nanotubes. Companies and NGOs should find ways to meet in the middle to better accomplish their goals, while regulators should strive for greater communication with industry.

Fig. 17: An Example of a Staged Framework for Managing Nanotech EHS Issues



Methodology

For this report, we conducted exhaustive secondary research on nanotech environmental, health, and safety risks. We also discussed the issues in in-depth, confidential interviews with 17 experts from industry, academia, and NGOs, with 10 officials at relevant regulatory agencies, start-up executives, academics, government agency representatives, NGO representatives, insurance company executives, and EHS officers at large corporations. Finally, we built and analyzed a catalog of peer-reviewed journal publications on nanomaterial EHS concerns, drawing on the database maintained by the International Council on Nanotechnology (ICON) at Rice University, literature searches using Science Citation Index, and bibliographies of review articles that cover the field.