REGULATING EMERGING TECHNOLOGIES IN SILICON VALLEY AND BEYOND

Lessons Learned from 1981 Chemical Spills in the Electronics Industry and Implications for Regulating Nanotechnology

A Report by the Silicon Valley Toxics Coalition (SVTC)
April 2, 2008
ABOUT SILICON VALLEY TOXICS COALITION (SVTC)

Silicon Valley Toxics Coalition is a diverse organization engaged in research, advocacy, and grassroots organizing to promote human health and environmental justice in response to the rapid growth of the high-tech industry.

We envision a toxic-free future, where each new generation of technical improvements in high-tech products includes parallel and proportionate advances in social and environmental justice.

Our goal is environmental sustainability and clean production, improved health, and democratic decision-making for communities and workers most affected by the high-tech revolution.

CREDITS

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Contributors: Vicki Bolam, Sheila Davis, Amanda Davison, Lauren Ornelas, Esperanza Sanz, Michael Starkey, and Meredith Williams.

Design and layout: Design Action
PERSON (~6ft tall)
2 billion nm

APPLE (~8cm)
80 million nm

ANT (~5mm)
5 million nm

diameter of a HUMAN HAIR
75,000 nm

smallest the EYE CAN SEE
10,000 nm

e. coli BACTERIA
2,000 nm

BUCKYBALL
1 nm

DNA
2 nm

diameter of a CARBON NANOTUBE
1.3 nm

MACRO

MICRO

NANO
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In an industrial gold rush that mirrors the semiconductor and biotech booms, Silicon Valley is rapidly emerging as the center for a host of new nanotechnologies. Nanotech is more than a single new industrial sector: It is transforming fields as diverse as electronics, medicine, environmental remediation, and solar energy, and it is already ubiquitous in a wide range of consumer products. By manipulating commonly used materials such as carbon, silver, gold, and polymers on the atomic and molecular levels, nanotech is exploiting the distinctive properties that many materials display at this extremely tiny scale. At the forefront of the nano boom is the so-called “clean tech” movement, applying nanotechnology to address global warming, the need for clean water, and other environmental problems.
The situation today is strikingly similar to that of the electronics industry in the early 1980s, when new “clean” manufacturing processes resulted in widespread groundwater pollution throughout Santa Clara County. The responses of industry, government, and environmental agencies to that crisis were woefully inadequate, due to major information and technology gaps.

The nanotech boom is generating an unprecedented number of new processes and materials that pose unknown potential environmental and health hazards. Unfortunately, U.S. regulatory policy has changed very little since the 1980s, and we now face similar gaps in our ability to protect public and environmental health. A 2006 study requested by California state legislators characterized these gaps in the environmental regulatory framework as follows:

- **Data Gaps**—lack of data on industrial materials, including their health impacts, environmental toxicity, and monitoring.
- **Technology Gaps**—lack of technologies and protocols for environmental and health monitoring, detection, and remediation.
- **Safety Gaps**—lack of coordinated, publicly available information about specific chemicals and materials, including where they are being produced and used.

This report provides a case study of the regulatory landscape faced by Santa Clara County in the 1980s and traces the clear and alarming parallels to today’s health and environmental regulations for nanotechnology. The paper concludes by outlining recommendations for policy reform based on closing existing gaps in data, technology, and safety. In support of these recommendations, we have included a set of sample questions (Appendix A) that communities can use to gather information about the use and safety of nanomaterials and processes in nearby facilities.

Although some progress is being made toward addressing these policy gaps, it is critical that we work toward the development of comprehensive state and federal chemical policies that protect public and environmental health. These policies should incorporate the “precautionary principle” as applied to recent environmental policy in the European Union. This principle requires those who advocate the use of new chemicals or processes to prove their safety, rather than requiring communities or workers to prove their dangers. Nanotech policies also need to address the impacts of nanomaterials throughout their lifecycles, from manufacturing through use and end-of-life disposal. We need to ensure that this new industrial revolution continues to benefit the regional, state, and national economies.
NANOTECHNOLOGY OVERVIEW

In 1959, Nobel Prize–winning physicist Richard Feynman challenged fellow scientists to start manipulating matter at the atomic level. He was among the first to realize that many commonly used materials exhibit entirely new—and potentially useful—characteristics at what we now call the “nanoscale.” Now, nearly 50 years later, the burgeoning nanotechnology industry is rushing to develop new materials and products using atoms and molecules as building blocks.

In a technology gold rush that mirrors the semiconductor boom of the 1970s and 1980s, nanotech is being applied to an ever-expanding array of medical, pharmaceutical, electronic, sensing, and environmental problems. It is also seeing increasing use in consumer products. At the forefront of the nanotech sector is the so-called “clean tech” movement, using nanomaterials and processes to tackle global warming and other environmental issues. These include the development of new solar technologies, energy-efficient products, environmental monitoring techniques, and water treatments.

Although nanomaterials are still typically entering the market as relatively simple applications (such as coatings and surfactants) and as passive additions to existing consumer products (such as cosmetics, sunscreens, and sporting goods), researchers are rapidly developing much more sophisticated and complex materials and uses. These include nanoscale cancer detection and drug delivery approaches that target individual cells; nanoscale computing and information technology; thin-film light emitting diodes (LEDs); and bioengineered molecular-level “machines” for tasks like medical monitoring and environmental remediation.

Much as the San Francisco Bay Area was the epicenter of the high-tech and biotech booms, the region is already a leading incubator for nanotechnology enterprises. The entrepreneurial spirit, abundant venture capital, and highly educated population of Silicon Valley make it ideal for the cultivation of new technologies, and there are at least 111 active nanotech companies and research facilities in the San Francisco Bay Area.

1. INTRODUCTION

The excitement and buzz surrounding this emerging industrial sector are only now being tempered by growing caution about its potential human and environmental hazards. New materials and processes are being rapidly developed and marketed without the regulatory and safety frameworks needed to protect human and environmental health.

APPLYING THE LESSONS OF SILICON VALLEY’S HISTORY

This situation is strikingly similar to that of the early days of the electronics industry in Silicon Valley, when new manufacturing processes touted as “clean industry” resulted in widespread groundwater pollution throughout the region. In 1981, the discovery of industrial chemical leaks from underground storage tanks at IBM and Fairchild Camera and Instrument led to an investigation of storage tanks at all the major companies in Silicon Valley. Leakage was pervasive. This contamination included chemicals such as trichloroethane (TCA), acetone, and Freon. Today Silicon Valley is still home to 29 “Superfund” sites (highly contaminated sites designated for cleanup under the federal 1980 Comprehensive Environmental Response, Compensation and Liability Act or CERCLA), and 179 contaminated groundwater locations that are the legacy of the industry’s infancy.

At the time of these leaks, San Jose’s population was plagued by high rates of birth defects and miscarriages. Although a definitive causal relationship was never established between the tank leakages and these health problems, federal lawmakers called the dismal local and federal response to widespread community concerns about health and genetic damage an “adventure into scientific no-man’s land. An adventure in which we rely on primitive charts and operate without a compass.”

Just as there were few regulations in the 1980s to address the dangers of electronics manufacturing chemicals, we now face a regulatory system that is outdated and ill-equipped to handle increasingly diverse and complex nanomaterials and processes. This report takes a hard look at the parallels between today’s nanotech industry and the semiconductor industry of the 1980s, outlining the environmental lessons to be drawn from the failures of that
earlier era. It examines the gaps in research data, technology, and environmental regulation that still exist and now hamper our ability to ensure the safety of the emerging nanotechnology sector.

The report concludes by outlining recommendations for policy reform based on closing existing gaps in data, technology, and safety. In support of these recommendations, we have included a set of sample questions (Appendix A) that communities can use to gather information about the use and safety of nanomaterials and processes in nearby facilities.

THE CHALLENGES OF REGULATING NANOTECH

Nanomaterials present an entirely new set of issues and regulatory concerns that are not addressed by the regulatory framework that was developed almost 40 years ago (and is still largely in place). In the 1970s, legislators could not anticipate the need to regulate engineered materials that are valued precisely because they are incredibly small. The 1976 federal Toxic Substances Control Act (TSCA) and other statutory and regulatory frameworks continue to regulate chemicals based on volume, typically exempting small quantities of materials. In addition, although materials at the nanoscale have properties that are completely different from their more common “bulk” forms, the current regulatory framework does not recognize them as new materials that require new evaluation.

Fortunately, we have an opportunity to learn from the past. Nanotech startups and established businesses are in a position to push for better understanding of the hazards of their industry. The industry is relatively new and still has a chance to work proactively rather than retroactively.

As we approach the regulation of these new technologies, it is important that we address potential hazards throughout the lifecycle of nanomaterials. Lifecycle analysis can assess both the short-term economic value of a technology, as well as the longer-term societal and environmental impacts. This approach is especially valuable with emerging products and markets, enabling regulators to address potential challenges and problems early in the product development process.

There are encouraging signs that legislators are beginning to address this need. In 2004, California State Senator Byron Sher, chair of the Senate Environmental Quality Committee, and Assemblymember John Laird, chair of the Assembly Committee on Environmental Safety and Toxic Materials, requested a study to address public and environmental health concerns, and to explore how to build long-term health and environmental safety into the design, production, and use of chemicals. This 2006 report, Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation, found that the existing environmental regulatory system is incapable of responding to developments in a proactive, deliberative way. The report concludes that chemical policy represents one of the major challenges of the 21st century, and that reorienting the existing approach to chemical regulations will require a long-term commitment to the development of a modern, comprehensive chemicals policy that includes the following goals:

- **Close the Data Gap**: Ensure that chemical producers generate, distribute, and communicate information on chemical toxicity, ecotoxicity, uses, and other key data.
- **Close the Technology Gap**: Support research, development, technical assistance, entrepreneurial activity, and education in green chemistry science and technology.
- **Close the Safety Gap**: Strengthen government tools for identifying, prioritizing, and mitigating chemical hazards.

In an attempt to address these issues, the California Department of Toxic Substances Control is hosting a series of public symposia on nanotechnology, the clean tech sector, and related environmental concerns. The October 2007 symposium, the second in the series, was titled Potential Hazards of Nanoparticles in the Environment, and brought together some of the nation’s leading nanotechnology researchers and technical experts. The Silicon Valley Toxics Coalition’s overarching goal is that nanotech companies, the government, and communities take effective action to protect public health and the environment. We owe it to the families who suffered from toxic exposure and fought for answers more than 25 years ago to demand that any claims to “clean tech” are truly clean and sustainable. Just as Silicon Valley is on the cutting edge of technological innovation, the region now has the historic opportunity to be at the “frontier of action” and take leadership in the development of modern environmental regulatory systems that keep pace with today’s rapid changes in technology.
WHAT IS NANOTECHNOLOGY?

OVERVIEW OF NANOMATERIALS

Nanoparticles are typically defined as ranging from 1 nanometer (nm) to 100 nm in size (a nanometer is a billionth of a meter—about 1/100,000 the thickness of a sheet of paper). For illustration, a hydrogen atom is about .1 nm. A DNA molecule, which carries genetic information in the cell, is about 2.5 nm long. A human hair is huge by comparison, about 50,000 nm thick; the head of a pin is about 1 million nm across. A sugar molecule, which measures about 1 nm, is about as big in relation to an apple as the apple is in relation to the earth.

Nanotechnology manipulates these incredibly small particles, essentially using atoms and molecules as the basic building blocks for new materials. In the simplest terms, “Nanotechnology is constructive; it snaps atoms together like Lego building blocks to build molecular structures in processes that are similar to, but potentially much more flexible and powerful than the processes used in biological systems.” Many nanomaterials occur naturally, but the nanotechnology industry revolves around engineered and/or manufactured materials targeted for specific uses. In fact, nanotech is far more than one new industrial sector. Nanomaterials and processes are being already widely used in consumer products such as cosmetics, food, and clothing, and they are also being applied to an ever-expanding array of medical, pharmaceutical, electronic, sensing, and environmental problems.

To say that a substance is “nano” does not merely mean that it is tiny; the prefix is also understood to mean that a substance has the capacity to act in fundamentally different ways. Altered properties can include color, solubility, material strength, electrical conductivity, and magnetic behavior. Put another way, it is well known that materials engineered or manufactured to the nanoscale exhibit different fundamental physical, biological, and chemical properties from bulk materials. One reason for this is that a different realm of physics, quantum physics, governs at the nanoscale. Another is that the reduction in size to the nanoscale results in an enormous increase of surface to volume ratio, giving nanoparticles a much greater surface area per unit of mass compared to larger particles.

Although Richard Feynman and others realized the potential of nanomaterials in the 1950s, it wasn’t until the 1980s that the development of sophisticated imaging equipment (such as the scanning tunneling microscope and atomic force microscope) made the manipulation of such materials practical. Nanomaterials encompass a broad range of chemistries, structures, and sizes, although many share some common attributes. For example, their typically high ratio of surface area to volume tends to make them highly reactive with other materials. A simple way to conceptualize the greater reactivity of increased surface area is to imagine starting a fire with wood. It is easier to light thinly cut wood shavings than larger pieces because more wood surface is available to react with the fire. Similarly, the smaller size and the more readily exposed surface area of many nanomaterials changes the types and rates of their reactions with other materials. This can be exploited in chemical applications, exposing a specific atom or molecule on a nanomaterial’s surface to facilitate its reaction with other chemicals. Three of the most common categories of nanomaterials are discussed below.

CARBON-BASED NANOMATERIALS

Much of the early work in nanotechnology involved carbon-based materials. Natural carbon is found in many different forms with a wide range of properties and industrial functions, including hard crystalline diamond, soft sheet-like graphite, and sooty carbon black. Buckminsterfullerene or “buckyballs” made headlines in 1985 when scientists at Rice University discovered particles formed by 60 carbon atoms that resembled Buckminster Fuller’s geodesic domes. The potential of these distinctive structures (which occur naturally and are now also being manufactured) is being explored for a range of applications, including drug delivery and fuel cells.

In 1991, carbon nanotubes were discovered by Sumio Iijima. These tiny tubes are formed of rolled-up sheets of carbon and can have very long lengths relative to their diameters. Carbon nanotubes have a wide range of properties that are already proving useful. They exhibit high electrical conductivity and high elasticity; they are 50
to 100 times stronger than steel; and their comparatively low density makes them lightweight relative to other materials that are traditionally used in similar applications. These properties give nanotubes many potential commercial applications, ranging from biomedicine, to nanoelectronics, to mechanical engineering. In one example, researchers are exploiting their long tubular structure to create “nanowires” in tiny devices. Carbon nanotubes are in wide production today, and they constituted a $50.9 million market in 2006.12

**METALS**

Bulk silver and gold have long been highly valued, and in their nano forms these relatively chemically inert materials become highly reactive and are ideal candidates for catalysts. For example, gold in its nano form can be used to bond to antibodies for cancer therapies, and these nanocatalytic metals are also being investigated for use in air cleaners, to enhance fuel cell performance, and for more advanced versions of catalytic converters on cars. Nanosilver is being incorporated into a wide range of consumer products due to its antimicrobial properties, and there is increasing concern that this expanding use of nanosilver could ultimately have damaging environmental and human health impacts (see “A Focus on Nanosilver” in Section 3 of this report).

Another widely studied nanomaterial is iron. When nanoparticles of iron are magnetically aligned, they create highly magnetic fields that can be used for sensitive medical imaging. Nanoiron is also being developed as a potential tool for environmental remediation of contaminants, to oxidize and break down toxic PCBs, dioxins, trichloroethylene, and other chemicals into less toxic materials. It can also potentially oxidize many heavy metals to reduce their solubility, thereby keeping lead, mercury, and other metals out of the food chain.

**POLYMERS**

Polymers have extensive potential in their nano forms (polymers are large molecules consisting of repeated chemical units, usually in a chain). One of the most basic applications is for use as membranes for water purification, power plant CO₂ emissions removal, and biological applications. Nanoscale membranes allow filtration and separation at smaller scales than conventional membranes. Dendrimers, a form of polymer, are being explored for use in drug delivery systems. These are globular chains of molecules that have branches radiating from a central point, with the number of branches determining the size of the overall particle. Researchers can control the physical and chemical properties of dendrimers during synthesis, and they are working to develop drug delivery systems with well-controlled solubility and control at the individual molecule level.
OVERVIEW OF POTENTIAL HAZARDS

The rapid expansion of patents and publications related to nanotechnology’s commercial applications far outstrips the amount of research related to its potential risks. From 1998 and 2007, the total number of research publications investigating nanotechnology was approximately 33,430; but only 656 of those addressed nanotoxicology and the potential risks related to these new materials and processes. The National Nanotechnology Initiative (NNI) had a FY07 budget of more than $1.39 billion, and the 2008 budget provides $1.44 billion. This raises the total investment since the NNI was established in 2001 to $8.3 billion and more than triples the annual investment since 2001. However, by the NNI’s own estimate, health and environmental implications (EHS) research is receiving just $58.6 million in 2008, or a mere 4 percent of the total amount.

Nanotoxicology research is critical because, just as the unique properties of nanomaterials are difficult to predict from the properties of their bulk form, the health hazards of nanoscale materials can be equally unpredictable. In the past, we have failed to anticipate the dangers of many widely used materials, including DDT, asbestos, benzene, and, more recently, flame retardants. Nanotech arguably presents even greater risk than these past “wonder” materials because, unlike them, it is not limited to one material or class of materials. Rather, it is platform technology crosscutting many industries, and it will soon be ubiquitous in manufacturing.

POTENTIAL INHALATION HAZARDS

Some potential hazards of nanomaterials can be readily foreseen. For example, small particles are associated with well-known diseases such as asbestosis and silicosis, granulomas, and lung inflammation, and some research indicates that the course of these diseases is influenced by particle size and shape. Based on this knowledge, we can expect that the inhalation of particles as small as engineered nanoparticles could be hazardous.

Carbon nanotubes, discussed earlier, are among the materials that raise concerns in this area. Single-walled nanotubes (SWNTs) are being studied to assess the relationship between particle size and toxicity—particularly respiratory toxicity. One study showed that nanotubes could penetrate deep into lungs due to their physical properties. Another study indicated that pulmonary problems could be greater with carbon nanotube exposure than for exposure to silica or carbon black. Researchers concluded that it would be prudent to advise a permissible exposure level for nanotubes that is below that for fine particles of quartz (such as dust generated when sawing or cutting quartz during industrial processes) until there is a more complete understanding of nanotube toxicity.

INCREASED REACTIVITY HAZARDS

Other predictable areas of potential nanotech hazards relate to the distinctive mechanisms and properties for which the materials are designed. As discussed previously, the increased available surface-area-to-volume ratio of nanoparticles tends to promote reactivity, and this increased chemical reactivity has been shown to increase production of reactive oxygen species (ROS), including free radicals. Free radicals or reactive oxygen species are highly reactive unstable molecules. The biological aging process is associated with an accumulation of free radicals in cells, and free radicals are also suspected to play a role in several cancers.

ROS and free radical production is one of the primary mechanisms of nanoparticle toxicity, and many types of nanoparticles have proven to be toxic to human tissue and cell cultures. These studies have shown increased oxidative stress, inflammation, and consequent damage to proteins, membranes, and DNA. ROS production has been found in a diverse range of nanomaterials including carbon fullerenes, carbon nanotubes, and nanoparticle metal oxides. While some nanomaterials (e.g., cerium oxide) are being explored as scavengers to rid the body of excess free radicals, nanogold, for example, has been...
found to accelerate creation of free radicals, and nanosilver may function in the same way.\textsuperscript{27}

The first scientific evidence of exposure to nanoparticle titanium dioxide resulting in production of reactive oxygen species in human brain cells was published in 2006, although it is still unknown whether the brain cells’ release of reactive oxygen species results in neuronal damage.\textsuperscript{28} Titanium dioxide nanomaterials have been shown to cause oxidative stress-mediated toxicity in a range of different cell types, including skin fibroblasts and human colon cells.\textsuperscript{29} In another alarming case, carbon fullerenes (buckyballs), used in face creams and moisturizers,\textsuperscript{30} have been shown to be toxic to human liver cells at low levels of exposure.\textsuperscript{31} Buckyballs have also been found to cause brain damage in fish,\textsuperscript{32} kill water fleas, and exhibit bactericidal properties.\textsuperscript{33}

**INCREASED MOBILITY AND BIOAVAILABILITY HAZARDS**

Due to their size, many nanoparticles have unprecedented mobility for a manufactured material.\textsuperscript{34,35} They readily enter the human body and gain access to the blood stream via inhalation and ingestion.\textsuperscript{36} It also appears likely that nanoparticles can penetrate the skin, although the jury is still out on that question, and more research is needed. Once inside the body, nanoparticles can cross biological membranes, cells, tissues, and organs more efficiently than larger particles.\textsuperscript{37} Once in the blood stream, nanomaterials can circulate throughout the body and can be taken up by organs and tissues, including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system.\textsuperscript{38} In addition, unlike larger particles, nanoparticles can be transported within cells and taken up by cell mitochondria and the cell nucleus, where they can interfere with cell signaling, induce major structural damage, and result in DNA mutation.\textsuperscript{39}

Because of these properties, the rapidly emerging use of nanomaterials for new ways of drug delivery is a major area of concern. These materials are being explored because they can be transported within the body to locations that have not been accessible with traditional medicines. In two key examples, nanomedicines hold great promise because they have the potential to cross the blood-brain barrier\textsuperscript{40} and enter the fetal bloodstream through the mother for therapeutic purposes.\textsuperscript{41} Although these particles are intended for delivery using very controlled methods, it is possible that other nanoparticles could also cross cellular barriers (buckyballs have been shown to do just that).\textsuperscript{42} Such transport could have unintended and undesirable consequences.

**A FOCUS ON NANOSILVER**

Inhalation hazards, increased reactivity, and unintended bioavailability may be foreseeable based on the various properties of nanoparticles, but other potential dangers may be more surprising. Silver in its bulk form is not toxic to humans and is often hailed for its antibacterial benefits. Nanosilver is already widely used as a protective antibacterial coating on pacifiers, handrails, socks, finger-nail clippers, and many other products. In its nano form, however, silver has been shown to behave quite differently. Nanosilver can cause damage to the part of the human cell that creates cellular energy (the mitochondria) and can also induce oxidative stress related to free radicals and cell membrane leakage.\textsuperscript{43} Human exposure to nanosilver, then, may pose a very different risk than exposure to the bulk silver in jewelry, for example.

In addition to human cellular risk, some environmental impacts of nanosilver can be predicted from bulk silver. For example, silver is very toxic to many invertebrates. In 1977, very low levels of silver in the southern San Francisco Bay were shown by U.S. Geological Survey researchers to have caused impaired reproduction in *Macoma balthica* clams. The silver had been introduced into the food web by unregulated disposal of photo processing waste. Only after a 95 percent reduction in the silver levels in the Bay (due to the Clean Water Act) did reproductive levels of these clams recover.\textsuperscript{44}

Nanosilver may also have a larger ecosystem impact. Research shows that nanosilver can disrupt the nitrogen balance in freshwater ecosystems through a process called eutrophication.\textsuperscript{45} Eutrophication results in a reduction of oxygen, which, in turn, drives competition at the bottom of the food web between algae types that can thrive with low oxygen and those that cannot. The resulting imbalance reduces the amount of available food for species throughout the food web.

Nanosilver is often fixed within a structural medium, but some products contain nanosilver particles distributed within fluids or creams. Particle-level release of nanosilver was touted as a fundamental product benefit when Samsung introduced its AgPlus or SilverCare silver sterili-
zation washing machine in 2003. The washer was designed with a system to generate and release nanosilver particles during the rinse cycle to coat laundry and disinfect it. Samsung claims that the machine will release “100 quadrillion silver ions into your cold-water wash,” thus saving energy while providing sterilization. Silver nanoparticles would then be present in the waste rinse water from these machines. In early 2006, EPA received letters from both the National Association of Clean Water Agencies (NACWA) and Tri-TAC, a technical advisory group for publicly owned treatment works in California, expressing concern with the growing number of household products that use pesticides for general antimicrobial purposes. Tri-TAC noted that this use of silver ran counter to long-standing pollution prevention efforts to eliminate silver in waste water.

Nanosilver has already been introduced so extensively that it could constitute a widely dispersed pollution source. It is possible that nanosilver could have impacts that will once again be felt by San Francisco Bay clams and, in turn, by those species that depend on the clams for food. More alarmingly, nanosilver exposure could start to impact cell function in humans.

Recent reports by the Natural Resources Defense Council and Friends of the Earth explored the nanosilver issue in depth.

CHALLENGES OF EVALUATING TOXICITY AND MEASURING EXPOSURE

Toxicity testing turns out to be far more challenging for nanomaterials than bulk chemicals. Traditionally, exposure is determined based on the bulk chemical properties of a material and the mass to which the subject is exposed. For nanoscale materials, many more factors affect toxicological potential—up to at least 16, in fact, including size, surface area, surface charge, solubility, shape or physical dimensions, surface coatings, chemical composition, and aggregation potential. This is a “far cry from the two or three usually measured.”

For example, toxic properties characteristic of a nanoparticle at one size may be different for the same nanomaterial at a different size. In addition, it has been found that nanotoxicity can be highly dependent on the purity of the nanomaterial in question and on what specific impurities (such as various heavy metals) are left by different production processes. For many nanoproducts, purity varies widely, depending on the manufacturing method and specifications.

These multiple factors add significantly more complexity to toxicology studies for nanomaterials, and therefore the tools used for nanotoxicology research must be specialized and modernized. In fact, nanotoxicology is an emerging field in its own right, underscoring the differences in determining nanomaterial toxicity. In an agenda-setting 2006 article in Nature, 14 international nanotechnology scientists put forth nanotechnology’s five “grand challenges,” which included the urgent need to develop methods for assessing nanotoxicity. Two recently published articles suggest new paradigms of predictive toxicology for engineered nanoparticle testing.

In addition, as noted in the case of nanosilver, above, evaluation of the health hazards of nanomaterials also requires new approaches to measuring exposure. Nanoparticles are frequently embedded in a composite or matrix, which allows the nanoparticle-level properties to be exploited on a larger scale. For instance, nanotubes—which are highly flexible, yet extremely strong—can be added to reinforce polymers and enhance their overall strength. In such cases, contact with the nanomaterial would most likely occur during manufacturing or be due to unintended use of the product or breakdown of the matrix during its use or disposal.

This potential for unintended exposure raises particular concerns when assessing the potential toxicity of nanomaterials throughout their lifecycles. No special requirements currently exist for manufacturers to determine the lifetime of standard products that are enhanced via nanomaterials. No special disposal requirements are in place, and the fate of the nanomaterials once the product is discarded is unknown. We are only beginning to address the end-of-life disposal of toxic electronics materials, and we may face a similar need for a lifecycle-analysis approach to products containing nanomaterials.
4. STATE OF NANOTECHNOLOGY IN THE SAN FRANCISCO BAY AREA

OVERVIEW OF REGIONAL NANOTECHNOLOGY

Because no centralized register exists of nanotechnology companies in the San Francisco Bay Area, it is difficult to quantify the number of companies or the total regional investment, but clearly nanotech is thriving. According to the Project on Emerging Nanotechnologies (PEN), San Jose, San Francisco, and Oakland are three of the nation’s top “Nano Metro” centers, with the region “emerging as the domestic frontrunner in nanotechnology competition.”

Many of the Silicon Valley’s most renowned companies have made large investments in nanotech within their core businesses or for new enterprises. Applied Materials announced its strategy for leadership in nanomanufacturing in its 2005 annual report. Hewlett-Packard’s Quantum Science Research lab focuses on advancing nanoscale electronics, while Chevron, Intel, Genencor, and other established companies have made substantial investments in nanotechnology. At the same time, there has been a proliferation of startups applying nanotech, and venture capital firms are devoting significant portions of their portfolios to the sector.

At the forefront of this expansion is the so-called “clean tech” sector, with a focus on applying new technologies to environmental problems. Nationwide, clean tech investments by U.S. venture capital firms in the first nine months of 2007 totaled $2.6 billion, already more than the $1.8 billion invested in all of 2006. The category is now the third-largest source of venture capital, and Silicon Valley is being heralded as the center of this promising new industrial sector, much of which centers on solar power technology.

The map below, compiled by the Silicon Valley Toxics Coalition (based on information from the Project on Emerging Nanotechnologies), provides an overview of Bay Area businesses, universities, and research organizations conducting significant nanotech operations.

It is difficult to assess to what degree nanotechnology and nanomaterials are actually being used by these companies. Some may simply use nano-based coatings as a minor part of their manufacturing process, and others may even claim a nano angle that they don’t actually have to enhance marketing. On the other hand, many operations rely entirely on nanotechnology. The breadth of nanotech companies reflects the broad diversity of technologies and expertise in Silicon Valley and in the region as a whole, but the following key sectors have emerged.
SEMICONDUCTORS
One could argue that the entire semiconductor industry shifted to a nanotechnology industry when the critical dimension of semiconductor devices fell below 100 nm. For the largest players in the industry, that transition occurred about five years ago with the move to 90 nm process technology. Intel and others currently have 65 nm devices in volume production and are aggressively pursuing ever-smaller device structures. All the supporting businesses associated with chip manufacture—processing equipment, lithography, materials supply, inspection systems, and design tools—have evolved to address the nanoscale needs of the industry. This has meant the development of materials and analytic equipment capable of performing at the nanoscale.

Micro-Electro-Mechanical Systems (MEMS) is the marriage of semiconductor technology with micromachining technology to produce mechanical or electromechanical devices. This sector relies heavily on semiconductor processes and nanotechnology. Bay Area companies in this sector include Applied NanoStructures, NxZilla (formerly Nanozilla), and SmallTech Consulting.

SOLAR ENERGY AND “CLEAN TECH”
The highly touted “clean tech” movement is one of the best-known nano-based industrial sectors and promises great advances to address global warming and other environmental problems. Several solar energy companies in the region rely heavily on nanotechnology in their design approach. Nanosolar uses semiconducting nanoparticles in ink form to manufacture photovoltaic (PV) cells for solar panels. This print-based approach enables them to manufacture a larger photovoltaic area than has been achievable using standard vacuum semiconductor deposition methods. Nanosys, NanoeXa, Miasole, and G24i are also using nanotechnology for solar cell applications.

Solar is not the only energy-related nano business with a regional toehold. Other nanotech-based energy applications being pursued are fuel cells (Kainos, PolyFuel), battery technology (Intematix), petroleum additives and catalysts (Accelergy), and clean energy businesses.

LIFE SCIENCES AND NANOMEDICINE
Startups throughout the Bay Area are working to develop a wide range of nanomedical products in the areas of pharmaceutics, drug delivery, and diagnostics, just to name a few. Trellis Bioscience is conducting antibody research using nanotechnology, and Fluidigm is developing equipment enabling biological researchers to work with the minute quantities of materials required for nanobiological applications.

ADDITIONAL INDUSTRIAL APPLICATIONS OF NANOTECH
A number of other nanotechnology applications are also well-represented in the region. For example, sensor technology is being advanced by companies like Lumiphore and Nanomix, and nanotech source materials such as carbon nanotubes are being supplied locally by Cnano Technology, Unidym, and Sun Nano.

GOVERNMENT RESPONSES TO NANOTECHNOLOGY: BERKELEY’S NANOTECH ORDINANCE
For the most part, unfortunately, local, state, and regional governments are jumping on the nano bandwagon, hoping to reap the economic benefits of these new technologies. However, some municipalities are striking a more cautionary note as they seek to protect their populations from potential hazards. On December 13, 2006, Berkeley passed a model ordinance requiring disclosure of manufactured nanomaterials produced within city limits. Researchers and manufacturers must now report what nanomaterials they are working with and how they are handling them. The ordinance applies no matter how small the quantities of nanomaterials involved; however, the Lawrence Berkeley National Laboratory and the University of California are exempt.

The concept of this ordinance is similar to other chemical exposure laws, such as the toxic notification portion of California’s Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986), and is consistent with the right-to-know goals of making environmental health information available to the public. Given the current lack of state or local nanotech regulation, more municipalities may take similar actions to address the regulatory void.
INTRODUCTION

Back in the 1970s and early 1980s, neither the residents of Santa Clara County nor their elected representatives anticipated the possibility that the region’s “clean” electronics industry could cause serious environmental pollution. Instead of high smokestacks spewing fumes, high-tech manufacturing was conducted in neat campus-like facilities. County officials felt twice blessed—enjoying strong economic growth and avoiding any apparent degradation of the region’s environmental quality. However, the illusion of a clean industry ended in December 1981 when IBM and Fairchild Camera and Instrument, two major electronics manufacturers, reported toxic spills at their local facilities. The “wet area around Fairchild’s underground tank” leaked acetone, isopropanol, toluene, exylene, and 1,1,1-trichloroethane (TCA). (See Appendix B for information about human impacts of these chemicals.) Tests confirmed that 60,000 gallons of TCA had reached downstream wells of the Great Oaks Water Company, a major supplier to the residents of Santa Clara County. Within a year, it was discovered that more than 80 percent of the underground chemical storage tanks located in the county were leaking, and that water used by more than 80,000 residents was contaminated. Ultimately, people living near the IBM and Fairchild toxic spills suffered 13 deaths and more than 267 medical problems, including birth defects, cancer, skin disorders, and blood diseases—all of which residents attributed to drinking water contaminated by those facilities.

GAPS IN ENVIRONMENTAL AND HEALTH DATA

When IBM located in San Jose in 1952 with 33 employees, the U.S. government had no inventory of chemicals in commercial use. By the 1960s, IBM had begun to use chemicals in many new ways to remain competitive in the disk drive market. By 1976, when the federal Toxic Substances Control Act (TSCA) was enacted, the IBM plant was among the biggest in the world, employing 12,000 at the facility and using approximately 550 chemicals on site. All of these chemicals were “grandfathered in” under TSCA, meaning that producers of chemicals were not required to disclose information on their toxicity.

Most of the chemicals in use by the industry were standard production chemicals and solvents, like acetone, isopropyl alcohol, and Freon®. All of these were commercially available, and many were commonly used in household products. The solvent TCA, used for cleaning magnetic disk drive parts, was also a common clothing spot remover and auto parts cleaner. The electronics companies followed all of the regulations for using these chemicals and even went beyond them, yet when more than 60,000 gallons of TCA spilled into the ground, the companies didn’t have any health data to show at what levels it could cause harm to human health and disputed the levels of cleanup required.

Industry representatives maintained that cleaning up the drinking water to a level of 10 parts per billion (ppb) represented an unreasonable approach, commenting that “TCA has roughly the same toxic effect on the central nervous system as alcohol, and remember that we all enjoy wine at 130 parts per billion.” There was very little data available to the public to prove otherwise. The California Department of Health Services (DHS) compared the health issues documented in the Los Paseos census tract, near contaminated Well 13 in the Great Oaks Water District, to an unexposed control census tract outside the district. They found a slightly more than twofold rate of spontaneous abortions, a threefold rate of malformations, and a high occurrence of low-birth-weight infants for the Los Paseos census tract, but it is a challenge to establish a definitive causal link to the leaks.

The DHS wanted to consider air quality in its investigation of human health impacts, but no air studies had been conducted on the chemicals that had been accidentally...
released. The companies did not have air-monitoring stations at their facilities, and in fact there was only one air monitoring station located in all of Santa Clara County, in downtown San Jose. With so little data, the DHS could not create a model of how much contaminated air was released nor determine its movement patterns.65

In the absence of regulations, industry was, by default, left to make its own determinations about permissible levels of exposures for nearby communities, for workers making the products, and for consumers using their products. In many cases these judgments were made hastily during the cleanup process, or balanced against profit margin without sufficient environmental or health data. For example, IBM typically depended on the chemical suppliers to provide data for the effects of chemical use in industrial environments, but the suppliers could not provide information on exposure in drinking water. IBM therefore conducted its own literature search to make a determination of safe levels of TCA in drinking water for San Jose residents.64

When Great Oaks Water Company president Betty Roeder contacted the director of the Regional Water Quality Control Board requesting information on standards for drinking water, she was directed to the head of the state health department, who eventually told Roeder that she and her customers were to decide on standards.65

At the time, several industry representatives testified that they would have preferred that legal standards had been available to eliminate the debate “between those who argue that any level of any chemical is harmful, and those who believe that the body can deal with small quantities.” Industry representatives also publicly commented that clear criteria for exposure and cleanup would have answered questions related to how much insurance the company needed, what they should have budgeted for cleanup, how best to keep the public informed, and how to measure cleanup progress.66

A similar argument has been made for establishment of clear criteria and legal standards for companies to collect and share occupational health-monitoring data and worker epidemiological or toxicological health studies with the public. Occupational health and safety scientists maintain that as early as 1982, IBM possessed sophisticated electronic medical and environmental monitoring systems, including the capacity to track chemical exposures against acute and chronic illness and death. Despite this capacity to conduct research, over the past 25 years few studies have been undertaken by companies or published.67,68 Nor have the health regulatory agencies required data collection that would facilitate such industry-wide epidemiology studies.

The lack of early standards for the collection and sharing of data among companies and with the public has led to many companies, such as IBM, keeping their worker health data files secret for 30 years. For example, in 2003 a suit against IBM involving two plaintiffs with cancer, James Moore (with non-Hodgkin’s lymphoma) and Alida Hernandez (with breast cancer) came before a jury in San Jose. The lawsuit represented one of more than 200 cases brought by former workers against IBM, alleging that chemical poisoning had resulted in cancer or other diseases. In addition to claims by IBM workers, more than 50 cases were brought by children of IBM workers who were born with disabling birth defects.69 The attorneys for Hernandez and Moore found out about IBM’s Corporate Mortality Files, which recorded the deaths of more than 31,961 IBM employees from 1969 to 2001. Although IBM attempted to block access to the internal files, claiming that they contained no helpful data, the court granted the workers’ attorneys access to the files.

John Hopkins University epidemiologist Richard Clapp studied the files for the plaintiffs and determined a higher-than-normal rate of breast cancer deaths in female manufacturing workers at the San Jose plant where the workers were employed. Clapp’s study also revealed that 7,703 male employees who had worked for IBM died from cancer, compared to 7,208 expected using the national average. The female cancer death total, 1,668, was also greater than the total predicted by the national average (1,455).70 The judge in the trial later ruled that the analysis of the IBM files was inadmissible as evidence on the grounds that the same study could have shown any number of things. The plaintiffs lost the case.

In 2004, publication of Clapp’s study in the academic journal *Clinics in Occupational and Environmental Medicine* was blocked when IBM objected to the use of corporate data that had been released only for use in the court case. Clapp was later able to publish the academic article after proving that IBM’s Corporate Mortality Files were already in the public domain and their contents cited in the *New York Times*. 
GAPS IN MONITORING AND CLEANUP TECHNOLOGY

In the 1960s, it had been determined that chemicals should be stored in underground tanks to safeguard against flammability. The tanks were coated to protect against corrosion, but they were not equipped with any external monitoring technology, and IBM and Fairchild possessed little knowledge of how the chemicals might behave once they entered the environment. Techniques for sampling water and air for contaminants were very crude or non-existent, and today’s requirements for environmental impact reports were still decades away.

Although IBM’s stated safety policy was to meet or exceed all government regulations and to establish stringent standards of its own when government regulations did not exist, the company was not required by law to monitor its tanks or to study the hydrogeology of the region. Such a study would have revealed the complex relationships between the area’s geology and groundwater movement that ultimately determined how the on-site pollution dispersed throughout the region’s underground water tables. In 1981, IBM began investigating its contaminated sites using newly available advanced modeling technology, which confirmed contamination of public and private wells in an area two-and-a-half miles long and two miles wide.

In fact, it was only during a 1980 construction project that IBM discovered that its chemical tanks were leaking acetone, petroleum naphtha, kerosene, isopropyl alcohol, and trichloroethane (TCA), and that these solvents had entered the soil and groundwater at one of the sites where the tanks were buried. Due to the lack of monitoring devices, IBM eventually had to dig up 55 tanks and visually inspect them for leaks. Ultimately, IBM replaced over two miles of underground pipes, 11,000 cubic feet of soil, and more than 55 underground tanks due to spills and leaks.

Nor was air monitoring technology readily available at the time. Well into the 1970s it was widely believed that small volumes of volatile chemicals would dissipate harmlessly into the air. In addition, it was common practice for truck drivers to flush their hoses out on the ground next to the underground tanks in order to make sure that the reagent-grade chemicals were not exposed to road dust. They thus inadvertently saturated the soil surrounding the tanks and contributed to the contamination of the groundwater.

A total lack of expertise on the part of the electronics industry and government in dealing with large quantities of chemicals in the groundwater also contributed to “delays and debacles” in the cleanup. For example, the cleanup process was delayed for 10 months as the Water Quality Control Board and the Air Quality Control Board failed to agree on a cleanup plan.

The Great Oaks Water Company had decided that the best course of action for cleanup was to sandbag the street, pump the well water into the street, then let the water flow down the street for 1,000 or 2,000 feet, after which it would flow into a storm drain. The water company hoped the TCA would evaporate before the water moved into the storm drains. Initially the air board said no to this proposal, but eventually agreed. After the 10-month delay, the cleanup plan was implemented. The contaminated water was pumped into the storm drain as planned, but the contaminated water unexpectedly permeated the Canoas Creek storm drain’s concrete bottom, seeping right back underground into the San Jose Water Company aquifer and ultimately exacerbating the cleanup problems.
GAPS IN HEALTH AND SAFETY

In the aftermath of the Fairchild and IBM spills, it was not clear to whom the public could turn for information on health, water safety, or the status of toxic cleanup. U.S. Representative Norman Mineta complained that he did not know where to send his constituents for basic answers about toxic substances in their drinking water: “To the county health department? To the Regional Water Quality Control Board? To EPA? Does anyone know?”

It was impossible for the community to get information about the health implications of drinking the water because the California Department of Health Services (DHS) had not conducted any health surveys or toxicological studies on the chemicals being used by high-tech companies in the region. Lorraine Ross, a frustrated Los Paseos resident, conducted an informal survey that showed high rates of cancer and birth defects in her neighborhood. This prompted the DHS to conduct an epidemiological study in 1982, which confirmed a high rate of spontaneous abortions in the community.

The public was scared, according to Great Oaks Water Company president Betty Roeder, who respected their fears and their problems, and admitted that she was scared too. As Roeder commented during a 1985 congressional hearing: “If I had it to do over again, I would tell the public what we know immediately, that is, right from the start.” However, there were no protocols in place for Roeder to release information, nor any formal methods for disseminating information about the safety of the water and the status of the cleanup. Public safety personnel responding to fires at facilities were also frustrated by their inability to get accurate information about the types of chemicals they would be dealing with in an emergency. Roeder also stated in her testimony: “I learned how strongly the public feels about their right to know. Also, now I look upon the public as an important aid in the struggle to keep government agencies on the ball. Believe me, there has been some indifference and some buck passing, and that problem continues to this day.”

The Silicon Valley Toxics Coalition (SVTC) was founded as a result of the frustration workers, public safety officials, and residents experienced when they were unable to obtain accurate and timely information from public agencies or companies. This strong coalition developed and passed landmark Emergency Planning and Community Right-to-Know ordinances. In 1986, SVTC campaigned with other environmentalists nationwide to persuade the U.S. Congress to pass the national Emergency Planning and Community Right-to-Know Act, which established reporting procedures for hazardous and toxic chemicals for the state, local governments, and industry. The Community Right-to-Know law also required EPA to establish an inventory of routine toxic chemicals emissions from facilities with 10 or more employees who use 10,000 pounds or more of hazardous chemicals listed by EPA. In addition, companies are required to prepare Materials Safety Data Sheets (MSDSs) that list each chemical’s common name and health impacts. The MSDSs are used by workers and emergency response teams to find out if a chemical is acutely hazardous, if the health impact is chronic, if it is a fire hazard, and how reactive the chemical is.

The Emergency Planning and Community Right-to-Know laws proved very useful at providing basic information—through a Toxic Release Inventory (TRI)—to local and state agencies for creation of emergency response plans. They also provided information for communities concerned about the health and environmental impacts of chemicals being emitted from local facilities. In 1985, SVTC compiled the newly available TRI information to show that 25 top companies were producing 12 million pounds of toxic chemicals in Santa Clara County. Based on these data, SVTC requested a reduction in the amount of chemicals dumped into the air and water annually. One of the companies took out a full-page ad challenging SVTC’s claims; however EPA confirmed that the numbers were accurate and derived from the TRI.
6. LESSONS LEARNED: CLOSING THE GAPS

CLOSING THE DATA GAPS

Chemicals “Grandfathered In”

- **Then:** The chemicals used at Santa Clara County’s electronics facilities in 1981 were already in commercial and household use in smaller amounts. The electronics companies introduced few new chemicals, but IBM and Fairchild introduced new ways to use and store these chemicals. Because the chemicals were “grandfathered in” under existing regulations, there was no requirement that chemical suppliers, electronics companies, water companies, or public agencies collect or share data on safe exposure levels for TCA or the other chemicals released into the drinking water.

- **Now:** Not much has changed in terms of the statutory or regulatory framework since the 1980s. Similar to the situation in the 1980s electronics industry, the vast majority of nanomaterials currently in commerce will most likely be grandfathered in under the Toxic Substances Control Act (TSCA) and treated as existing materials. For example, if a nanomaterial contains the same molecules as one of the 80,000 conventional chemicals already in the TSCA inventory, then (according to EPA’s 2007 TSCA concept paper) it will be treated as that existing chemical and not considered a “new” chemical.28

Despite their novel properties and the associated unknown risks, EPA has not classified nanomaterials as new substances for assessment and regulatory purposes, pursuant to TSCA or any other statute. This means that the producers of chemicals are not required to disclose to EPA any information on their toxic and ecotoxic properties prior to manufacturing; local regulatory agencies are not required to track companies or to monitor potential releases into the air, water, or soil; and communities and local governments operate under the misguided assumption that because the companies are following the law, community health is being protected.

Such “grandfathering” also ignores nanomaterials’ fundamentally different properties (their very nanoneis) and the risks these new properties may pose. It ignores the fact that these substances are patented for their novelty, their legally recognized distinct differences from their larger counterparts. It ignores the billions of dollars being spent to develop the new, fundamentally different, and enhanced properties of these substances. Industries—not to mention the U.S. government, which is spending well over $1 billion annually on nanotech—are banking on the simple fact that “nano” doesn’t mean merely tiny. In fact, nano is best understood to mean that a material has the capacity to be fundamentally different. Yet our regulatory agencies have thus far not recognized that reality in any meaningful way for adequate oversight.

Lack of Environmental Monitoring

- **Then:** After the 1981 spills, the DHS wanted to consider air quality in its investigations of human health impacts, but no air studies had been conducted on the chemicals that were accidentally released. Due to a lack of air monitoring stations, the DHS could not create a model of how much contaminated air was released nor determine its movement patterns. Neither the County of Santa Clara nor the Water Quality Control Board kept an inventory of where the tanks were buried or required any routine testing for leakage. In 1983, less than two years after the water contamination, “SVTC organized to pass the toughest safety standards in the country for preventing gas releases and helped win community right-to-know laws that required companies to disclose the chemicals they discharge into the community.”29 In response to the spill, the county passed two cutting-edge ordinances at the behest of the community. The Model Toxic Gas Ordinance encouraged companies to minimize the use of toxic gases, regulated toxic gas storage and handling, and provided information for fire safety personnel responding to emergency situations. The Hazardous Materials Ordinance required secondary containment and strict monitoring of underground tanks.

- **Now:** By today’s standards, it may appear absurd that the Regional Water Quality Control Board and local governments did not know where tanks filled with hazardous materials were buried in the community. However, today there are no public agencies collecting or monitoring air or water data for nanomaterials in...
Santa Clara County, nor could they do so adequately, as discussed below, due to limitations on cost-effective technology. Facility-based laws such as the Clean Water Act (CWA) and Clean Air Act (CAA) may be effective for regulating nanotechnologies in theory—however neither law requires that any special attention be paid to nanotechnologies or nanomaterials as a class. Controls on hazardous air pollutants (HAPs) typically apply only to sources that emit certain volumes of pollutants, and this test may not be an appropriate metric for nano-releases. In order to lower the volumetric threshold, EPA would be required to make certain discretionary findings with respect to a nanomaterial’s potency and potential for bioaccumulation.

EPA also has the option of listing certain nanomaterials as toxic water pollutants, thereby enabling local agencies to impose monitoring and technological controls. However, these are data-driven statutes, and data is in short supply for nanomaterial releases and potential impacts, thereby hamstrung agencies. Because nanomaterial releases continue, any further delay in taking action to monitor potential air and water releases risks a repeat of history, with the health of local communities compromised as a result of unknowingly being exposed to hazardous substances.

Lack of Health Data

- **Then:** IBM’s compilation of Corporate Mortality Files proved that electronics companies had the technical capacity and financial resources to collect occupational health data and to create evaluation systems without unreasonable expense to the company. If other companies had been collecting and sharing this information, many health risks could have been prevented. However, there was no legal reporting requirement for the type of data IBM was collecting. The regulatory system, in fact, discouraged companies from sharing this data, due to concern that the company might put itself at a competitive disadvantage if other companies weren’t required to share the same type of data. They were also concerned that making the data public would result in exposure to legal liability. According to Joseph LaDou, a UC San Francisco clinical professor of medicine, “Ideally the semiconductor industry should have begun monitoring the health of its employees relative to their work environment from the time the companies were formed—taking coordinated, proactive steps to reduce exposures and prevent chronic disease.” LaDou and other occupational health scientists believe that “given their [IBM’s] technological capabilities, such an effort would have been entirely feasible and realistic, and had they implemented such programs, the health problems that are now surfacing in the high-tech industry might have been averted.”

- **Now:** Inadequate data on potential environmental and human health risks compounds the challenge of analyzing the ability of existing laws to address nanomaterials and makes it difficult to determine the specific limitations and gaps of these laws. This dearth of data stems in large part from the inadequate federal funding provided for EHS study of nanomaterials to date. Although high-tech companies have proven reluctant to voluntarily submit health data, the U.S. Environmental Protection Agency (EPA) continues to depend on voluntary measures as a means of monitoring the health of workers and the health of communities with high concentrations of nanotech companies. EPA recently launched a voluntary Nanoscale Materials Stewardship Program under the Toxic Substances Control Act (TSCA). EPA is inviting interested parties to participate in a “basic” program by submitting existing data on the engineered nanoscale materials they manufacture, import, process, or use. Although there is routine data used in the field of epidemiology and other health professions, EPA has developed an optional form for participants to use. EPA is also inviting interested parties to participate in an “in-depth” program to test engineered nanoscale materials they manufacture, import, process, or use. Similar voluntary programs initiated in the E.U. have met with dismal results. Thus far the U.K. government’s voluntary program received only a half-dozen submissions from nanotech companies and Denmark’s voluntary program produced such a meager response the government declined to publish the results. A private-sector partnership between Environmental Defense and DuPont has established a voluntary framework that has precisely one company participating—DuPont—and only one chemical has been fully reviewed by the framework.

Critics of the voluntary program have also expressed concern that EPA is moving too slowly for such a rapidly developing technology, and that its program delivers too little, too late. The program has been in the development stage for almost three years and will not deliver its detailed evaluation for another two years. “It lacks deadlines for participation, for launch, or for evaluation, and fails to require concurrent development of
mandatory TSCA oversight measures.” In the meantime, EPA continues to fail to provide basic information to workers or take even rudimentary steps to coordinate federal occupational health and safety agencies to share information and make it publicly available. AFL-CIO industrial hygienist William H. Kojola recently stated that the Occupational Health and Safety Administration (OSHA) has not developed standards, guidance, or fact sheets and has failed to even provide a link on its website to the extensive information developed by the National Institute for Occupational Safety and Health (NIOSH). “Given the potential hazards nanoparticles can pose, the AFL-CIO believes the federal government should use a precautionary approach and issue nano-specific regulations to safeguard workers and use this opportunity to get this right to protect workers, the environment, and the public.”

CLOSING THE SAFETY GAPS

Lack of Monitoring Technology

- **Then:** IBM and Fairchild did not have adequate tank monitoring equipment to determine if the underground tanks were leaking. The companies had limited detection technology to determine how much material was released into the environment and largely depended on visual inspections for chemical leaks. There was limited air and water monitoring equipment or computer modeling technology available to determine the movement of volatile chemicals such as TCA in different environmental media. This lack of knowledge and technology resulted in the initial spill and the subsequent spread of pollution to other water supplies during the cleanup process.

- **Now:** A similar lack of monitoring equipment exists today with respect to nanomaterials. Instruments to detect and monitor the movement of waterborne nanomaterials in the environment are not expected to be available until 2012. A universal aerosol system for monitoring airborne nanostructured materials is not projected to become available until 2010. Development of robust systems for evaluating the health and environmental impacts of engineered nanomaterials over their life will be available in 2012, and models for predicting engineered nanomaterials in the body are predicted for use by 2017. In sum, despite widespread use and disposal of nanomaterials, we currently lack cost-effective technologies to monitor, measure, detect, and control these materials and to remove them once released.

That said, the electronics companies in the 1980s did not have the benefit of more than 40 years of technological development in environmental science. The nanotech industry has the opportunity to draw from historical experience and to utilize new environmental methods. These include green chemistry principles (the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances); biomimickry (a new science that studies nature’s best ideas and then imitates these designs and processes to solve human problems); and lifecycle assessment tools. The nanotech industry has an opportunity to invest in innovative detection and monitoring technology for the development, production, and end-of-life management of products.

CLOSING THE TECHNOLOGY GAPS

CLOSING THE SAFETY GAPS

**Then:** In the 1980s, more than 1,297 electronics companies were located in Santa Clara County. Five of the county’s municipalities were among the top 10 ranking cities where electronics companies were located. Despite this concentration, little attention was paid by the local environmental and public safety agencies to the safety of the industry as it expanded. Emergency response agencies did not have information regarding dangerous chemicals in use, and health departments had not collected data nor conducted health surveys addressing the human health impacts of chemicals being used in close proximity to residential areas. Thus, once TCA and other chemicals were discovered in groundwater, the agencies were ill-prepared to respond.

The lack of information caused fear and frustration among water company representatives, as well as community and public backlash against the electronics industry. In 1985, a local TV public opinion poll showed that 81 percent of the residents were afraid to drink the tap water, and 95 percent felt that water companies should regularly test the tap water. In addition, 87 percent of those polled said that the industry should be shut down until it cleaned up its pollution.

Because there was no formal process for the public to get answers to their questions, neighborhoods began to take matters into their own hands, conducting their own health surveys, compiling their own data, and hosting their own meetings to bring the community up to date about the spill and the cleanup process. Although the public may have an important role “in the struggle to keep government agencies on the ball”
(as Great Oaks Water Company president Betty Roeder put it), the passage of the local Community Right-to-Know Act demonstrated that the public also needs to be guaranteed good data and transparency from government agencies and companies.

Now: Currently, it is not clear how federal, state, or local regulators will inventory nanomaterials in use at local facilities or if nanomaterials will be included in the Community Right-to-Know laws and the Toxics Release Inventory (TRI). In 2007, SVTC conducted more than 15 interviews with state and local regulators and found a lack of clarity on how nanomaterials should be regulated.

According to a State of California Department of Health Services (DHS) Hazard Evaluation System and Information Service (HESIS) expert, the Materials Safety Data Sheets (MSDSs) provide a first defense for workers; but these are inadequate in the case of nanotechnology. MSDSs only require reporting for materials that are 1 percent or more of the mass of the bulk material. Worse still, many MSDSs are grossly misleading for nanomaterials and their potential risks. For example, carbon nanotubes have been found to be classified as graphite on MSDSs. Graphite is not an appropriate safety reference standard for carbon nanotubes, since carbon nanotubes display very different mass-based dose-response relationships and lung histopathology when compared directly with graphite.

A U.S. EPA pollution prevention officer said, “There is no way of knowing where it’s [nanotechnology] being produced.” There are no TRI reporting requirements for most nanomaterials because, for most facilities, nanomaterials use falls below the volumetric threshold of 10,000 pounds or more annually. The lack of TRI reporting will make it almost impossible for local residents, environmental regulatory agencies, and emergency response teams to collect the needed information to protect public health and safety.

Frustrated by the resistance of local nanotech research facilities to provide information requested by the city, the Toxics Management Division of the City of Berkeley’s Planning and Development Department recommended that the city pass an ordinance requiring nanotech facilities to report their material use. However, according to the U.S. pollution prevention officer, without a coordinated effort and standard procedures for collecting the information, “It’s hard to know if the City of Berkeley will get much useful information and what they can do with it.”

Although California is frequently promoted as a state “well positioned to compete, and lead, in the nanotechnology age,” state policymakers have done little to prepare California’s environmental and health regulatory agencies for the onslaught of new nanotech companies.

An expert from the California Environmental Protection Agency (Cal/EPA) who was interviewed suggested that more health research is required, but added that the state has “no handle” on how current nanochemicals are transported, produced, or used in California. The regulator also said that “There’s no process for evaluating chemicals in consumer products. It’s a low priority relative to, say, E. coli in spinach.”

Most of the regulators interviewed said that they depend on EPA for information. However, EPA has not provided local or state agencies with information regarding where the facilities are located, what type of materials are in use, or the development of health surveillance or measurement tools.
7. FEDERAL ENVIRONMENTAL REGULATORY GAPS AND IMPLICATIONS FOR REGULATING FACILITIES USING NANOTECHNOLOGY

SUMMARY OF FEDERAL ENVIRONMENTAL REGULATIONS

Following the 1981 IBM and Fairchild chemical spills, congressional representative James Oberstar said the spills represented a microcosm of the country’s toxic and hazardous waste dilemma:

“…we have conflict of laws, Federal and State laws [and] overlapping layers of Federal laws…we have regulatory agency problems; we have an inadequate health database, we have [a] lack of knowledge about the effects of toxic substances on human health and on the environment in which those chemicals have escaped. In short, we literally stand in this area of leaking underground storage tanks and the hazardous chemicals that escape from them—we literally stand on the frontier of knowledge, and on the frontier, also, of action and response to the situation.”

Oberstar could easily have made the same remark today about emerging nanomaterials. The current landscape with respect to environmental knowledge about nanotechnology is eerily similar to the landscape of the 1960s for basic chemicals. Regulation lags far behind the industry commercialization curve, we lack monitoring and detection technology, and no cleanup practices have been established. Right-to-know laws do not appear effective. Most of the U.S. environmental laws enacted in the 1970s and early 1980s were in response to environmental crises. According to a 2006 report from the California Policy Research Center (Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation), federal chemical policies still don’t provide EPA with sufficient authority to require the generation of information on chemical toxicity and ecotoxicity and the distribution of that information to state governments, businesses, industry and the public.

While the U.S. government depends on a 40-year-old framework, the European Union has provided global leadership in developing new approaches to evaluating chemicals before they are placed on the market. The E.U.’s Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) law, enacted in June 2007, aims to improve protection of human health and the environment by giving industry more responsibility for managing the risks from chemicals and for providing safety information on the substances used. Manufacturers and importers will be required to gather information on the properties of their chemical substances (which will allow their safe handling) and to register the information in a central database run by the European Chemicals Agency (ECHA) in Helsinki.

As previously noted, nanotechnology is having an impact on a broad range of industrial sectors, from food and agriculture to cosmetics, medicine, and so-called “clean tech.” Because of this, as many as several hundred environmental laws may be affected by the introduction of nanotechnology. Following is a brief summary of the laws discussed in this report, with references to some of the outstanding research published by experts on nanotech and the U.S. environmental regulatory framework.

TOXIC SUBSTANCES CONTROL ACT (TSCA): GAPS IN FEDERAL CHEMICAL POLICY REGARDING NANOMATERIALS

The Toxic Substances Control Act (TSCA) provides the U.S. Environmental Protection Agency (EPA) with authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical if there is a “reasonable basis to conclude the chemical represents or will represent an unreasonable risk of injury to health or the environment.”

TSCA is the only U.S. regulation addressing chemicals both before and after they enter commerce. Many other laws (such as the CERCLA, RCRA, Clean Air Act, and Clean Water Act) are based on how chemicals are identified in TSCA. In addition, state and local environmental regulations are based on federal legislation.

TSCA has not significantly changed since 1976, and it is clearly in need of modernization to address emerging new
materials and environmental issues, especially those related to nanotechnology. Recently published reports that outline the policy gaps and potential for utilizing TSCA include the following:


**POTENTIAL REGULATORY GAPS IN THE RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)**

The Resource Conservation and Recovery Act (RCRA) regulates the handling, reuse, recycling, storage, treatment, and disposal of solid waste, including hazardous waste. Some waste nanomaterials will be classified as hazardous waste under the existing rules, either as listed hazardous waste or under specific toxicity characteristics. However, there are the following barriers:

- The RCRA focus on mass as a determinant of regulatory coverage is not necessarily appropriate for nanowastes.
- Disposal of most consumer waste that contains nanomaterials is likely to be exempt from the hazardous waste regulations because such products will be considered as household waste.
- Research is needed to determine whether existing practices for handling, treating, storing, and disposing of bulk forms of solid waste are appropriate for nanoscale waste of the same chemicals.
- Many generators of nanowaste lack sufficient information to provide to owners or operators of treatment, storage, and disposal facilities to enable them to manage such waste appropriately.

The following reports provide additional information on the current status of nanowaste regulation:


**NANOMATERIALS AND THE CLEAN WATER ACT (CWA) AND CLEAN AIR ACT (CAA)**

Facility-based laws such as the Clean Water Act (CWA) and Clean Air Act (CAA) may be effective for regulating nanotechnologies, particularly if an information disclosure approach is used. However, neither act requires that any special attention be paid to nanotechnologies. In addition, the acts rely heavily on monitoring and on new protocols that may be expensive to implement.

- **Hazardous Air Pollutants**: Nanomaterials are not currently listed as hazardous air pollutants (HAPs), but EPA could add them to the list after making a discretionary decision that considers emissions, ambient concentrations, bioaccumulation, or deposition. However, control requirements for HAPs typically apply only to sources that emit certain volumes of pollutants, and this test may not be an appropriate metric for nano-releases. In order to lower the volumetric threshold, EPA would be required to make certain discretionary findings with respect to a nanomaterial’s potency and potential for bioaccumulation.

- **Toxic Water Pollutants**: EPA has the option of listing certain nanomaterials as toxic water pollutants, thereby enabling the agency to impose tight technological controls. This would require EPA to make determinations as to toxicity, persistence, degradability, and additional factors.

The following reports provide an overview of the status of the CWA and CAA relative to nanotechnology regulation:


POTENTIAL REGULATORY GAPS IN THE COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT (CERCLA OR SUPERFUND LAW)

CERCLA was enacted in 1980 in response to highly publicized cases in which hazardous waste disposal sites were improperly managed and hazardous substances were spilled, causing contamination that put people at risk of disease or injury. The act gives the federal government the authority to respond to releases of hazardous substances into the environment. The statute also authorizes the federal government to sue persons who are responsible for release to compel them to perform the cleanup. The so-called Superfund statute defines “hazardous substances” to include RCRA hazardous wastes, certain substances regulated under the Clean Water Act, hazardous air pollutants under the Clean Air Act, and certain chemical substances or mixtures regulated under TSCA. Additional information about the role of CERCLA in regulating nanotechnology can be found in the following report:


EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT (EPCRA)

The Emergency Planning and Community Right-to-Know Act (EPCRA) was enacted in 1986 to provide information to citizens about hazardous chemicals in their communities. The Toxics Release Inventory (TRI), a key component of EPCRA, requires owners and operators of certain facilities to report to EPA when certain toxic chemicals are released from the facility into the environment. According to EPA, TRI data provide communities “more power to hold companies accountable and make informed decisions about how toxic chemicals are managed. The data often spurs companies to focus on their chemicals management practices since they are being measured and made public. In addition, the data serves as a rough indicator of environmental progress over time.” Although it appears that many commercial and federal nanotechnology facilities could be covered by TRI, it is unclear whether EPA could or would use the authority provided to it in the statute to add Standard Industry Classification codes that would include additional facilities that manufacture, process, or use nanomaterials. Additional discussion of the role of EPCRA in regulating nanotech can be found in:


OCCUPATIONAL HEALTH AND SAFETY ADMINISTRATION (OSHA)

The U.S. Occupational Safety and Health Administration (OSHA) is an agency of the United States Department of Labor. It was created by Congress under the Occupational Safety and Health Act in 1970 to prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules (called standards) for workplace safety and health.

The difficulties with using OSHA to deal with nanomaterials are the same issues that arise with most of the environmental statutes. Detection of nanotechnology products requires expensive and sophisticated equipment, and it is often unclear which parameters are the relevant ones to measure from the standpoint of toxicity. For practical purposes, whether in the setting of a factory or the ambient environment, detection and control methods (e.g., filters) may not be currently available or may be too expensive or too cumbersome. For an overview of the potential impact of nanotechnology on worker health, see the following article:

8. RECOMMENDATIONS

The summary below is from Principles for the Oversight of Nanotechnologies and Nanomaterials.
This collaborative declaration on urgently needed oversight principles for nanomaterials was prepared by an NGO coalition that included SVTC, and was initially released in August 2007. The complete Principles document, now endorsed by over 80 organizations spanning six continents, is available at numerous endorsing organizations’ websites, including that of the International Center for Technology Assessment, www.icta.org.

We believe governments must act in accordance with the eight fundamental principles necessary for adequate and effective oversight and assessment of the emerging field of nanotechnology:

I. A Precautionary Foundation: Product manufacturers and distributors must bear the burden of proof to demonstrate the safety of their products: if no independent health and safety data review, then no market approval.

II. Mandatory Nano-specific Regulations:
Nanomaterials should be classified as new substances and subject to nano-specific oversight. Voluntary initiatives are not sufficient.

III. Health and Safety of the Public and Workers:
The prevention of exposure to nanomaterials that have not been proven safe must be undertaken to protect the public and workers.

IV. Environmental Protection: A full lifecycle analysis of environmental impacts must be completed prior to commercialization.

V. Transparency: All nano-products must be labeled and safety data made publicly available.

VI. Public Participation: There must be open, meaningful, and full public participation at every level.

VII. Inclusion of Broader Impacts: Nanotechnology’s wide-ranging effects, including ethical and social impacts, must be considered.

VIII. Manufacturer Liability: Nano-industries must be accountable for liabilities incurred from their products.
In addition, the following specific recommendations are based on the lessons learned in the electronics industry:

1. Nanomaterials should be treated as new materials (rather than “grandfathered in”), and they should be subject to EPA’s new chemicals program: Taking a lesson from the earlier high-tech industry (which caused new problems when it used common chemicals in new ways), special attention should be paid to the storage, transportation, monitoring, and modeling of nanomaterials.

2. Environmental monitoring and remediation technologies should be developed in conjunction with new facility installation: The lack of environmental monitoring and detection technology led to the chemical spills of the 1980s and to delays in subsequent cleanup. EPA should require that companies using nanomaterials include the development of monitoring and remediation technology as part of any new facility.

3. California chemical policy reform should make special provisions for emerging technologies: California is currently reviewing its chemicals policy. State efforts to target nanotech and “clean tech” as growth industries should also include the development of new ways for state agencies to coordinate health and environmental data collection, health studies, environmental monitoring and detection technology, public information and education, and emergency response to accidental releases. A delay in taking steps to coordinate these efforts will result in a repeat of the “debacles and delays” of the 1980s, should such accidental releases occur.

4. Include nanomaterials in emergency planning and community right-to-know reporting requirements: Provide workers, emergency personnel, and communities with information about nanomaterials being generated and used at local facilities. Requiring the inclusion of nanomaterials in Toxic Release Inventories (TRIs) and Materials Safety Data Sheets (MSDSs) will increase public knowledge and access to information about the presence of nanomaterials in the community. It will also facilitate the ability of states and communities working with nanotech facilities to improve chemical safety and protect public health and the environment.

5. EPA rule-making authority should be used to ensure that regional water and air quality control agencies have the authority to implement monitoring controls on nanotech facilities: EPA has the option of listing certain nanomaterials as toxic water pollutants, thereby enabling local agencies to impose monitoring and technological controls. Any further delay in taking action to monitor potential air and water releases risks a repeat of history and poses a danger to public health.
9. CALL TO ACTION

“If I had it to do over again, I would tell the public what we know immediately, that is, right from the start. I have learned how strongly the public feels about their right to know. Also, now I look upon the public as an important aid in the struggle to keep government agencies on the ball.”

–Great Oaks Water Company President Betty Roeder, at a 1985 congressional hearing investigating toxic spills in Santa Clara County.

Here are some steps you can take to help hold the nanotech industry accountable and avoid a repeat of the environmental disasters of the 1980s.

1. Support mandatory labeling requirements: Insist that the labeling for products you purchase includes information about any nanomaterials they contain.

2. Support requirements that manufacturers of products containing nanomaterials take responsibility for worker and consumer safety throughout the product lifecycle: This includes safety in manufacturing, use, and end-of-life disposal and recycling.

3. Support the Principles for the Oversight of Nanotechnologies and Nanomaterials:
   Go to www.nanoaction.org or www.icta.org and have your organization sign these principles to show your support for the international movement that lays out clear guidelines for responsible and sustainable development of nanotechnology. Press for governments and businesses to also adopt the principles.

4. Ask local nanotech companies to work with nearby communities to complete community action questionnaires (see Appendix A) and take steps to protect community health: The U.S. EPA does not currently require nanotech companies to take important steps needed to protect public health. Therefore, communities must protect the health of their members and the environment by going directly to companies to ensure that they are collecting the necessary health data and that proper health studies have been conducted on their products and/or processes. Communities should also ensure that state-of-the-art environmental and health monitoring systems are installed so that companies can detect accidental releases, track emissions, and develop emergency cleanup and response plans.

5. Pass community right-to-know laws in your community: If companies are unresponsive to community requests for information, the next step is to approach local elected officials and request laws supporting community access to information about what chemicals are being used and the dangers posed by any accidental release into the environment.

6. Help SVTC build a Community Right-to-Know Registry of nanotech companies in your community: EPA is not currently inventoried or registering nanotech communities, and state agencies don’t know where they are located. Help SVTC develop and share information about the locations and activities of nanotech companies in your area.
APPENDIX A

NANOTECHNOLOGY HEALTH AND ENVIRONMENTAL IMPACT

COMMUNITY ACTION SURVEY TOPICS/QUESTIONS (SAMPLE)

SVTC has developed a comprehensive survey to gather information from companies and institutions that currently produce and use nanomaterials. Examples of the survey topics and questions are below; the full survey will be complete soon and available at http://www.svtc.org/nanocompany_survey. Community advocates are encouraged to use these questions to collect information from nanocompanies and other institutions operating in their areas. If the company or university does not have this information or is unwilling to work with the community to collect the information, then they should not be allowed to operate in the community.

Sample Topics from the Nanomaterials Survey

1. Information about the company and its facilities, including company name, location, contact person, phone number, and a description of the activities that go on at each facility.

2. What chemicals and nanomaterials are currently in use at the facility?

3. Identify the precautions and cleanup plans the company has made, if any, to protect nearby communities from exposure to harmful substances.

4. Determine what studies the company has conducted on nanomaterials to determine toxicological and epidemiological risks for nearby communities.

5. Does the company have technology to detect and monitor nanomaterials, including those in the environment already and those being released by their facility?

6. Has the company established standards for permissible levels of exposure for chemicals and nanomaterials?

7. Identify whether or not the company is conducting any environmental monitoring, such as air, water, or soil testing, to evaluate their use of nanomaterials and establish baselines.

8. Determine whether or not the company has performed a lifecycle assessment of the nanomaterials used and has an end-of-life management plan for the products produced.

9. Will the company make the lifecycle assessment information available to the public?

10. Does the company conduct worker bio-monitoring at the facility?
Acetone, Isopropanol, Toluene, Xylene and 1,1,1-Trichloroethane are solvents that can be used to clean microscopic dirt and dust off of chips.\textsuperscript{103} All of these chemicals present dangers to human health.

**Acetone**—Short-term exposure effects include eye, nose, and throat irritation. It can also cause the shortening of menstrual cycles. Long-term exposure can lead to kidney, liver, and nerve damage, birth defects, and lowered ability to reproduce in males.\textsuperscript{104}

**Isopropanol**—Exposure to isopropanol can cause eye irritation, dermatitis, nausea, vomiting, depression of the nervous system, unconsciousness, and even coma or death due to respiratory failure.\textsuperscript{105}

**Toluene**—Toluene exposure can cause headaches, confusion, memory loss, and some hearing loss. High levels of exposure during pregnancy may cause neurological problems and retarded growth and development in the child.\textsuperscript{106}

**Xylene**—Short-term exposure to high levels of xylene can lead to skin, eye, nose, and throat irritation, difficulty breathing, impaired memory, headaches, dizziness, confusion, damage to the liver and kidneys, and even death. It can also lead to harmful effects in pregnant mothers and fetuses.\textsuperscript{107}

**1,1,1-Trichloroethane**—Exposure to 1,1,1-trichloroethane can cause dizziness and loss of coordination. Exposure to high levels may cause unconsciousness, decreased blood pressure, and the heart to stop beating.\textsuperscript{108}
ENDNOTES


6 See note 1 above.


16 Ibid.


20 See note 23 above.


25 See note 24 above.

26 See note 36 above.


30 See note 27 above.


35 Letter from Chuck Weir, Chair, Tri-TAC, to James Jones, Director, Office of Pesticide Programs, Environmental Protection Agency, January 27, 2006. Available at http://www.tritac.org/letters.htm


41 Andre Nel, et al., “Toxic Potential of Materials at the Nanolevel,” Science 311:622, 2006; See also