Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 23 No. 33 July 25, 2008

NANOTECHNOLOGY: IS NEW REGULATION NEEDED, AND IF SO, BY WHOM?

by

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The U.S. Environmental Protection Agency (EPA) defines nanotechnology, in part, as "the creation and use of structures, devices and systems that have novel properties and functions because of their small size."[1] In this context, "small size" means *very* small. A nanometer is one-billionth of a meter. A human hair is roughly 80,000 to 100,000 nanometers wide. Nanotechnology structures range from 1 to 100 nanometers in any direction. The theory of nanotechnology began in a 1959 talk by physicist Richard Feynman, and the science became a reality in the 1980s with the invention of special microscopes that allow scientists to see how atoms and molecules behave in various conditions. Manipulation of the conditions with heat, moisture, electromagnetism, and chemicals causes the atoms and molecules to form new shapes.

Nanotechnology takes several basic forms: creating extremely small particles or crystals of an existing substance such as silver; building never-before existing shapes such as spheres or tubes from molecules of carbon; building polymers from branched units that create cavities in which other molecules can be placed; and combining nanoparticles with other nanoparticles or with material on a larger scale. A nanoparticle behaves differently than the same substance on a different scale. For example, silicon is an insulator on a larger scale but a conductor on the nano scale; aluminum is stable on a larger scale but explosive on the nano scale. Similarly, engineered nano-structures have properties unlike any other previously known matter. For example, carbon nanotubes, one atom thick and 10,000 atoms long, are 100 times stronger than steel but eight times lighter. Woven into sheets or mixed with composites, carbon nanotubes have the potential to revolutionize the construction industry.

There are nanotechnology companies in almost every industrialized country, including several thousand companies in the U.S. Estimates of the total sales of products incorporating nanotechnology in 2007 range from $50 billion to $88 billion. Analysts forecast that by 2014 products incorporating nanotechnology will be 15% or more of all global manufacturing, worth $2.6 trillion. The hundreds of products using nanotechnology currently on the market include medical devices, cosmetics, sunscreens, foods, computers, and clothing, with new products being added at the rate of three or four per week. One index currently lists over 600 available products, produced by over 320 companies located in 20 countries.[2]

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[1]EPA, Science Policy Council, Nanotechnology White Paper, February 2007, at 5, http://www.epa.gov/ord/lrp/pdfs/epa-nanotechnology-whitepaper-0207.pdf.

[2]The Nanotechnology Consumer Products Inventory of the Woodrow Wilson International Center for Scholars (WWICS),

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The EPA's February 2007 Nanotechnology White Paper described that point in time as the end of a six-year-long first generation of basically passive structures, and the beginning of a second generation of active structures such as solar cells and targeted drugs. Robotic devices are expected by the third generation, in the next 10-15 years, followed by a fourth generation of molecule-by-molecule design and self-assembly capabilities. It is then expected that the fourth-generation nanotechnologies will be integrated with other cutting-edge sciences such as information technology and biological technology with results that are presently unimaginable.[3]

Along with the promise of expanded knowledge and increased commerce, nanotechnology has raised concerns about health and safety in the workplace, for consumers and for the environment in general. The concerns about the effect on the human body arise from characteristics of nanoparticles such as the ability to penetrate skin and, if inhaled, to diffuse throughout the respiratory system. Once in the blood, particles could rapidly reach sensitive organs and even cross the blood-brain barrier. If ingested, nanoparticles could end up in various organs and could be excreted in urine.[4] Moreover, the increased surface-area-to-volume ratio of nanomaterials make them more reactive than the same substances in other forms. Some experiments have shown that nanomaterials can cause cell damage in laboratory animals, but very little is presently known about the possible toxic effects of various nanomaterials or how those materials might accumulate and interact in the atmosphere, in soil, and in water.[5] Those who believe that there is little cause for concern point out that nanoparticles can exist naturally, from striking a match or frying food or in ocean waves, and that the hemoglobin in our blood operates on a nano scale. Others, however, believe that the consequences of widespread introduction of such particles into the environment should have been more thoroughly investigated before the proliferation of products reached the market. A recent experiment showed how "odor fighting" socks can release ionic silver during ordinary laundering; aquatic ecosystems could be damaged if the silver travels through wastewater treatment and enters natural waterways.[6]

The U.S. government has not yet enacted regulatory or environmental laws directed specifically at nanotechnology. The consensus of the U.S. legal community and regulatory agencies appears to be that the challenges presented can be dealt with under existing federal regulatory schemes. The American Bar Association[7] and various federal agencies have analyzed how current agencies, such as the FDA and OSHA, and current laws, such as the Toxic Substances Control Act (TSCA), the Clean Air Act, and the Clean Water Act, might regulate this new technology. The U.S. Office of Science and Technology Policy (OSTP) and the Council on Environmental Quality (CEQ) developed a set of principles to guide the development and implementation of policies for health, safety and environmental oversight by federal agencies.[8] However, some citizens' groups and other commentators warn that there are potential gaps in the existing regulatory framework, and emphasize the public's right to know about nanotechnology manufacturing and any possible health risks.[9] The OSTP/CEQ principles have been criticized on various blogsites as giving higher priority to promoting nanotechnology than to protecting health and the environment and as mistaken in the conclusion that no changes are needed in federal

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http://www.nanotechproject.org/consumerproducts. Many of the products listed incorporate nanoparticles of silver for antibacterial effect, and many of the products are targeted at children.

[3]White Paper, *supra* note 1, at 12-13.

[4]*See* T. Bell, *Understanding the Risk Assessment of Nanotechnology*, http://nano.gov/Understanding_Risk_Assessment.pdf.

[5]*See* White Paper, *supra* note 1, at 29-62 for a discussion of research to date and the need for additional research.

[6]*See* Science Daily, Apr. 7, 2008, at http://www.sciencedaily.com/releases/2008/04/080406175050.htm.

[7]A committee of the ABA Section of Environment, Energy, and Resources has published 7 nanotechnology briefing papers, including papers analyzing the adequacy of regulation under several federal statutes. In phase II, launched in October 2007, the committee will publish papers analyzing additional federal statutes. *See* http://www.abanet.org/environ/nanotech/.

[8]Text of the Nov. 8, 2007 memorandum is at http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf.

[9]*See, e.g.*, S. Davis, *History tells us we need better oversight of nanotech facilities*, San Jose Mercury News, Apr. 22, 2008, http://www.mercurynews.com/opinion/ci_9011245?source=email; *Regulating Emerging Technologies in Silicon Valley and Beyond, A Report by the Silicon Valley Toxics Coalition*, Apr. 2, 2008, available at http://www.etoxics.org.

  ISBN 1056 3059

statutes.

The EPA has awarded numerous grants to universities to investigate health and environmental effects of nanomaterials, as well as grants to fund research on the use of nanotechnology for environmental protection and remediation. A myriad of organizations has generated an enormous body of literature on the public policy aspects of nanotechnology. The focus of U.S. research institutes and manufacturers has been on industry self-regulation, by entities such as the International Council on Nanotechnology (ICON), launched by the Center for Biological and Environmental Nanotechnology at Rice University.[10] In June 2007, the European Union (EU) enacted the Registration, Evaluation, Authorisation and Restriction of Chemical Substances law (REACH) which requires manufacturers and importers to gather information on the properties of substances and register that information with a central database.[11] Some commentators argue that the U.S. should enact similar requirements. In contrast, the EPA recently launched its Nanoscale Materials Stewardship Program (NMSP) which invites participants to voluntarily report available information on the engineered nanoscale materials they manufacture, import, process, or use.[12] The EPA says it will use its authority under the TSCA to keep the information confidential, but reporting companies could be liable if their reports reveal violations of existing regulations.

A federal research and development program, the National Nanotechnology Initiative (NNI), was created in 2001 as a multi-agency effort to insure U.S. leadership in nanotechnology, and through the 2009 budget will have invested nearly $10 billion. Investment by the U.S., Europe, and Asia has been roughly equal in recent years, and analysts suggest that private investment has exceeded government investment since 2006. The 21st Century Nanotechnology Research and Development Act of 2003 requires the National Nanotechnology Advisory Panel (NNAP) to periodically review the NNI and, in April 2008, the NNAP issued its Second Assessment and Recommendations.[13] Also in April 2008, the U.S. House of Representatives Committee on Science and Technology held hearings in connection with the National Nanotechnology Initiative Amendments Act of 2008. Some witnesses testified that the U.S. has been spending far too little on risk research (and far less than Europe has spent).

More than half of the U.S. states have enacted statutes related to nanotechnology.[14] However, no state has yet enacted any laws aimed at regulating nanotechnology. Instead, the legislation considered and statutes enacted have been measures to establish study commissions, to support education (by funding facilities and projects, endowing professorships, developing curricula), and to provide economic incentives (by grants, tax credits against income taxes and franchise taxes, tax credits for investments). In at least one state, California, a multi-agency team has begun to study ways to minimize risks of manufacture and use of nanoproducts.[15]

The city of Berkeley, California, has enacted an ordinance regulating nanotechnology, and the city of Cambridge, Massachusetts,[16] is considering adopting a similar ordinance. In December 2006, Berkeley amended

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[10] *See* http://cben.rice.edu and http://icon.rice.edu. The mission of ICON is to assess, communicate, and reduce environmental and health risks associated with nanotechnology while maximizing its benefits to society.

[11] *See* http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.

[12] *See* http://epa.gov/opt/nano/stewardship.htm for details of the program launched in Jan. 2008. In the same month, the EPA published a Draft Nanomaterial Research Strategy, available at http://es.epa.gov/ncer/nano/publications/index.html.

[13] President's Council of Advisors on Science and Technology, The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel, available at http://www.nano.gov.

[14] The National Conference of State Legislatures ("NCSL") reported in June 2006 that 29 states had considered legislation and 22 states had enacted or adopted legislation related to nanotechnology. *See* http://www.ncsl.org/programs/lis/legislation/NanoLegislation2006.htm for description of specific legislation. A March 2008 search of each state's legislature website and enacted statutes revealed that the more recent legislative activity falls in the same categories as that listed by the NCSL in June 2006.

[15] Oct. 3, 2007 news release from the California Department of Toxic Substances Control, http://www.azonano.com/News.asp?NewsID=5053.

[16] *See* Jan. 8, 2007 City Council Resolution at http://www.cambridgema.gov/cityclerk/PolicyOrder.cfm?item-id+16916.

  ISBN 1056 3059

an existing ordinance that already required handlers of hazardous waste to file written disclosures. The added language states, "All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases, and mitigate such materials."[17] The first reports were due June 1, 2007 and Berkeley indicated that it had received one full report and two partial reports (from UC Berkeley and the Lawrence Berkeley National Laboratory, which responded but did not include the data specified in the ordinance). Berkeley issued guidelines for the new requirements in August 2007.[18]

A March 2008 publication[19] argues that many state and local governments can and should take action, under enabling laws permitting such action, to fill gaps in federal regulation and oversight, by analogy to earlier state and local action related to air, water, waste, labeling, and worker safety. On the other side of this question, some argue that piecemeal local regulation could create inconsistent and conflicting standards, making it difficult for businesses to comply. State and local officials have been quoted as saying that they believe action by the federal government is unlikely in the foreseeable future and therefore they feel compelled to pursue regulation at these more local levels. The Berkeley City Council stated that the goals of the 2006 ordinance included putting pressure on the state and federal government and also increasing participation in a public dialogue. Recent surveys have indicated that a very large proportion of the U.S. population knows little or nothing about nanotechnology. The television series on nanotechnology that was broadcast by PBS in April 2008, and other initiatives for public education, may increase awareness of the growing presence of nanotechnology and foster a consensus on the need for additional research and regulation. Public concern could lead to states and cities enacting or proposing regulatory measures and that in turn could lead to national legislation. Industries are likely to favor preemptive national regulation to avoid the inconsistencies of localized regulations.

The challenge for governments of every level is to balance the goals of encouraging innovation and avoiding harm. The NNAP's April 2008 second assessment warns that "nanotechnology is losing a public relations contest,"[20] a conclusion supported by a review of the commentary on numerous Internet websites. The NNAP assessment and the recent congressional testimony alike call for an overhaul of the federal approach to create a comprehensive "top-down" framework for research of environmental, health, and safety impacts as the basis for decisions on further regulation. Failure to adequately address these issues at this critical time could lead to consumer rejection of nanoproducts similar to the EU moratorium on genetically modified food products and could undo the developing economic benefits of this promising technology.

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[17]Municipal Code §§ 15.12.040, 15.12.050. Text of ordinance at http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure.pdf.

[18]Text at http://www.ci.berkeley.ca.us/uploadedFiles/Planning_(new_site_map_walk-through)/Level_3_-_General/Manuffactured%20Nanoscale%20Materials.pdf.

[19]S. Keiner, *Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology*, 52-page report published by the WWICS Project on Emerging Technologies, available at http://www.nanotechproject.org/publications/archive/room_at_bottom/. Ms. Keiner's report contains much useful information on, *e.g.*, locations of U.S. entities working in nanotechnology, current status of federal oversight, historical action by states to adopt environmental standards more stringent than federal standards, and scenarios under which state and local governments could adopt regulations.

[20]Assessment, *supra* note 13, at 25-26.

  ISBN 1056 3059