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The New Business of Nanotechnology: Exploring Commercial Opportunities and Risks

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Abstract

There is an Alice-in-Wonderland awe associated with nanotechnology. While the technology is both exciting and hopeful for many good reasons, for businesses, and the lawyers who counsel them, the lack of certainty in areas involving potential risk is unsettling. The U.S. Environmental Protection Agency (EPA) is only now beginning to think through how best to apply the authority it has under the traditional environmental statutes, and to adopt regulatory programs and policies to address the potential risks and regulatory challenges nanotechnology invites. While research is progressing briskly on key hazard and exposure nanotechnology issues, much remains to be done leaving commercial applications of nanotechnology in new, unsettled waters. This article identifies some of these challenges and the non-conventional, innovative ways that

lawyers, business managers, risk assessors, and others must embrace to manage risk and avoid liability effectively.

Notes

[1]National Nanotechnology Initiative, “What is Nanotechnology?.” http://www.nano.gov/html/facts/whatIsNano.html (accessed February 22, 2008).

[2]EPA, Nanotechnology White Paper (February 2007), 5. http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (accessed February 22, 2008).

[3] See Lux Research, The Nanotech Report™, 4th Ed. (2006), iii.

[4] Toxicology studies of certain ultrafine particles demonstrate that smaller particles have potential to induce oxidative stress and inflammation in the respiratory tract and cardiovascular systems. See G. Oberdörster, E. Oberdörster, and J. Oberdörster. Nanotechnology: An emerging discipline evolving from studies of ultrafine particles. Environ. Health Perspect. 113(7) (July 2005):823.

[5] See EPA, “Nanotechnology under the Toxic Substances Control Act.” http://www.epa.gov/oppt/nano/ (last updated February 22, 2008).

[6]See FDA, “Nanotechnology.” http://www.fda.gov/nanotechnology (accessed February 22, 2008).

[7] See NIOSH, “NIOSH Safety and Health Topic: Nanotechnology.” http://www.cdc.gov/niosh/topics/nanotech/ (accessed February 22, 2008).

[8] See NTP, “NTP Nanotechnology Safety Initiative.” http://ntp.niehs.nih.gov/go/nanotech (last updated February 28, 2006).

[9] See United States Naval Research Lab, “Nanoscience and Technology.” http://www.nanosra.nrl.navy.mil/ (accessed February 22, 2008).

[10] See EPA, “Nanotechnology: Research Projects.” http://es.epa.gov/ncer/nano/research/index.html (last updated February 12, 2008).

[11] Project on Emerging Nanotechnologies, Woodrow Wilson Center for International Scholars, “Consumer Products: An Inventory of Nanotechnology-Based Consumer Products Currently on the Market.” http://www.nanotechproject.org/inventories/consumer/ (accessed February 22, 2008).

[12] Small Times Magazine (March 2005).

[13] These are accounting rules used to prepare and report on financial statements for public and private companies.

[14] Swiss Re, Nanotechnology—Small Matter, Many Unknowns (2004), 48. http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf (accessed February 22, 2008).

[15] Robert Blaunstein, PhD. Unfamiliar exposure, Insurance Networking News 10(4) (Nov. 2006):13–14. http://www.insurancenetworking.com/issues/20061101/4372-1.html (accessed February 22, 2008).

[16] For another review of emerging risk from the insurer's perspective, see Lloyd's Nanotechnology: Recent Developments, Risks and Opportunities (2007). http://www.lloyds.com/NR/rdonlyres/7C1D8222-A3E8-4781-8C80-7FFABFC3F59E/0/Nanotechnology_Report.pdf (accessed February 22, 2008).

[17] 73 Federal Register 4861 (January 28, 2008).

[18]See 70 Federal Register 24574 (May 10, 2005). The EPA convened a public meeting to discuss various options in June 2005. The discussion at the public meeting yielded a consensus that a voluntary program on existing engineered nanoscale materials would have significant value. Shortly thereafter, the EPA created an interim ad hoc work group on nanoscale materials (Work Group) as part of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a federal advisory group tasked with advising OPPT on TSCA and pollution prevention matters. On November 22, 2005, after the Work Group had met several times, NPPTAC submitted to the EPA Administrator its Overview Document on Nanoscale Materials, which outlined a framework for a EPA approach to a voluntary program for engineered nanoscale materials and a complementary approach to new chemical nanoscale requirements under TSCA, and addressed various other

issues pertinent to engineered nanoscale materials. NPPTAC, Overview Document on Nanoscale Materials (November 22, 2005). http://www.epa.gov/opptintr/npptac/pubs/nanowgoverviewdocument20051125.pdf (accessed February 22, 2008).

[19]Letter from James B. Gulliford, Assistant Administrator for Prevention, Pesticides & Toxic Substances, to Stakeholders (October 18, 2006). According to the letter, the EPA's goal is “to implement TSCA in a way that enables responsible development of nanotechnology and realizes its potential environmental benefits, while applying sound science to assess and, where appropriate, manage potential risks to human health and the environment presented by nanoscale materials.” http://www.epa.gov/oppt/nano/nano-letter.pdf (accessed February 22, 2008).

[20] See 72 Federal Register 38079–38085 (July 12, 2007). All the notices and accompanying documents are available at http://www.epa.gov/opptintr/nano/nmspfr.htm (accessed February 22, 2008). The first notice solicited public comment on the EPA's proposed Information Collection Request under the Paperwork Reduction Act, including a draft form that NMSP participants could use to submit data to the EPA; the second announced a public meeting on the NMSP; and the third solicited public comment on two draft documents: (1) the “Concept Paper for the Nanoscale Materials Stewardship Program under TSCA”; and (2) the “TSCA Inventory Status of Nanoscale Substances—General Approach.”

[21] The amendment is available at http://www.ci.berkeley.ca.us/citycouncil/ordinances/2006/6960.pdf (accessed February 22, 2008).

[22] The recommendation is available at http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure.pdf (accessed February 22, 2008).

[23] See ISO, “TC 229: Nanotechnologies.” http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983 (accessed February 22, 2008).

[24] See ASTM, “Committee E56 on Nanotechnology.” http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/COMMITTEE/E56.htm?E+mystore (accessed February 22,

2008).

[25]OECD, “About the OECD.” http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html (accessed February 22, 2008).

[26] A complete copy of the Framework and other related information are available at http://nanoriskframework.com/page.cfm?tagID=1095 (accessed February 22, 2008).

[27] Completed worksheets for the three DuPont demonstration projects—TiO_2, CNTs, and nano-Fe^0—are available at http://nanoriskframework.org/page.cfm?tagID=1326 (accessed February 22, 2008).

[28] Responsible NanoCode, “Background to the Responsible NanoCode.” http://www.responsiblenanocode.org/index.html (accessed February 22, 2008).

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