



CITY OF BERKELEY'S ORDINANCE REGULATING NANOTECHNOLOGY RAISES KEY ISSUES

The City of Berkeley, California has enacted the nation's first local ordinance regulating the production and use of manufactured nanoparticles.¹ Effective December 15, 2006, the ordinance amends the Municipal Code's hazardous materials title to require manufacturers, researchers and other businesses to file written disclosure plans that identify their production or use of nanoparticles, disclose toxicity data, and provide plans for safe handling and disposal. Although Berkeley's ordinance applies only within the City's limits, it has been cited as a model for similar legislation by other localities and, possibly, state governments.

PROVISIONS REGULATING MANUFACTURE OR USE OF NANOPARTICLES

The ordinance is designed to regulate the rapidly developing field of nanotechnology, by which engineered particles or structures in the range of one to 100 nanometers² are created and manipulated. Nanomaterials have been shown to have unique and valuable properties, including great strength, electrical conductivity, and a wide range of biological and medical applications. Federal spending on nanotechnology research exceeds \$1 billion annually, and hundreds of products employing nanotechnology reportedly are on the market. Because health and safety research for nanotechnology remains at an early stage, concerns have been widely voiced as to the potential risks posed to humans, bio and environmental resources exposed to engineered nanomaterials.

Berkeley's ordinance amends two section of the Municipal Code. First, it adds a new subsection to Section 15.12.040, the omnibus provision mandating the filing of specified disclosures by "[e]ach handler, or facility under the jurisdiction of the City of Berkeley, that handles hazardous material or waste in a quantity subject to disclosure" under the Code.

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¹ Municipal Code, §§ 15.12.040, 15.12.050.

² A nanometer ("nm") is one billionth of a meter.

The subsection 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.

Second, the ordinance amends Section 15.12.050 to require that the mandated disclosure plan be filed regardless of the quantity of nanoparticles involved: "All manufactured nanoparticles, defined as a particle with one axis less than 100 nanometers in length, shall be reported in the disclosure plan."

Apart from its definition of "manufactured nanoparticle" as a "particle with one axis less than 100 nanometers," the ordinance contains little detail or guidance spelling out the particular materials intended to be regulated, the scope and specific content of the mandated disclosures, or how the submitted information will be utilized by the City to address health and safety concerns. Municipal Code provisions treat information submitted pursuant to the hazardous materials title as presumptively available to the public, although submitting parties may request confidential treatment for trade secrets or other confidential business information.

ISSUES POSED

Particularly because the City has portrayed its ordinance as a model for nanotechnology enactments by other local and state jurisdictions, it is instructive to consider several of the key issues raised by its provisions.³

Application to all manufactured nanoparticles. Under the federal Toxic Substances Control Act (TSCA), the EPA possesses broad authority to regulate "new" chemicals, including requiring premanufacture notification, toxicological testing, and authority to impose limits on their production, distribution and use in appropriate cases. To date, EPA has moved cautiously in applying its TSCA authority to nanoscale materials. In November 2006, an EPA official stated that the agency is working to produce a public paper specifying how TSCA will be applied to nanoscale materials, but that EPA does not believe reducing an existing chemical to nanoscale necessarily creates a "new" chemical for TSCA purposes. "Nanoscale Manufacture of Existing Chemical Does Not Make It 'New,'" EPA Official Says," Bureau of National Affairs (BNA) Daily Report for Executives, at A-10 (November 21, 2006). EPA has been working with chemicals having

nanoscale dimensions for years, he stated, and the majority do not pose additional or unanticipated risks. *Id.*

In sharp contrast, Berkeley's ordinance applies to the production or use of *any* manufactured particles with one axis below 100 nm in any amount.⁴ In fact, because its definition of "manufactured nanoparticle" is not limited to materials fabricated using nanotechnology techniques and intended to have different and unique characteristics by reason of their small size, the ordinance may be construed to extend to a variety of commonly used materials produced through ordinary manufacturing procedures that contain some nano-sized particles.⁵

⁴ A report submitted to the City Council by the Community Environmental Advisory Commission, which helped develop the ordinance, states that the "proposed ordinance only addresses nanoparticles that are engineered materials created for a specific purpose." December 5, 2006 memorandum, received at 12/05/06 Council Meeting, at 1. However, the ordinance contains no language expressing such a limitation or providing criteria to determine when man-made materials at the nanoscale will be deemed "engineered materials created for a specific purpose."

⁵ Manufactured products not produced using nanotechnology techniques but that contain nano-sized particles include perfumes, pigments, inks, some drug ingredients and some processed food products. Carbon black, produced since the 1860s and used extensively in rubber products, pigments and plastics, contains large numbers of nanoparticles. Operation of diesel engines and metal grinder processes, frying foods, and even the striking of an ordinary match, release nanoparticles. Nanoparticles exist in nature in ocean spray, volcanic ash, clouds and clay.

³ The City's hazardous materials manager reportedly stated: "We're hoping others will use this format and duplicate it in health and safety codes around California." *Los Angeles Times*, "Berkeley puts nanotechnology under hazardous materials law" (December 15, 2006), at C2.

No sound scientific basis exists to support the City's evident conclusion that any and all man-made materials having nanoscale dimensions require regulation because they potentially threaten human health or the environment.

Lack of sufficiently detailed compliance requirements.

Due to the rapid development of nanoscience and technology, assessing the "current toxicology of the materials reported" is likely to prove a costly and burdensome exercise. This is particularly true for small technology companies or startup businesses engaged in nanoscience research or invention with no commercial applications on the immediate horizon. Yet, the ordinance offers little if any useful guidance as to the quantity or quality of toxicity information required, and in what format. Similarly, in calling for submittal of plans as to how a facility will "safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate" nanomaterials, the ordinance fails to provide even basic instructions as to what is required.

Lack of secure confidentiality protection. Because application of the ordinance is triggered by any use or production of manufactured nanoparticles regardless of quantity, its requirements apply just as much to research and development programs

as to commercial production. Yet the information to be submitted in satisfaction of these requirements is presumptively available to the public, and businesses are expressly forbidden to withhold commercially sensitive information. Municipal Code, § 15.12.110(F). While the submitting party may request confidential treatment for trade secrets or other proprietary information, it is up to the City's hazardous materials manager or a court to grant such protection. *Id.*, § 15.12.110 (A-D). Understandably, businesses engaged in nanotechnology research or invention are likely to find the absence of assured confidentiality protection a matter of grave concern.

Ambiguity as to the application of other "hazardous materials and waste" requirements. Due to the manner in which the amendments are incorporated into the Municipal Code's hazardous materials title, it is possible to read them as subjecting any user or manufacturer of manufactured nanoparticles to the full array of the City's regulations governing the reporting, handling and disposal of hazardous materials and wastes. At the very least, the City's hazardous materials manager who administers these provisions appears to have considerable discretion to treat all or some manufactured nanoparticles as subject to these requirements notwithstanding the

absence of evidence establishing any genuinely hazardous properties of such materials.

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Berkeley's ordinance is the result of two years of study by the City's Community Environmental Advisory Commission, prompted by health and safety concerns arising from nanoparticle research to be conducted at the Lawrence Berkeley National Laboratory. The Commission's report describes the proposed amendments as "a minimum regulation for nanotechnology facilities."

Very likely, Berkeley's ordinance stems from a perception by City officials that federal or state regulation expressly tailored to nanotechnology is overdue. However, the significant issues raised by its ordinance illustrate the dangers of piecemeal local regulation of a rapidly developing industry that is national, or international, in scope. Local regulation often provides little meaningful protection to consumers and residents, but can create inconsistent and conflicting standards for businesses located within the affected jurisdiction. Since Berkeley's ordinance has been offered as a model for regulation by jurisdictions elsewhere, companies involved with nanotechnology will need to monitor this, and possibly other, efforts by local authorities to regulate this important industry.

UPDATE: CAMBRIDGE, MASSACHUSETTS LOOKS TO BERKELEY'S NANOPARTICLE ORDINANCE AS A MODEL

At the time the Berkeley nanoparticle ordinance was enacted, representatives of the City expressed a hope that their ordinance would serve as a model for other jurisdictions. At least one city has already responded to Berkeley's example.

On January 8, 2007, the City Council of Cambridge, Massachusetts adopted the following resolution:

WHEREAS: The use of subatomic materials as microscopic building blocks for thousands of consumer products has turned into a big business so quickly that few are monitoring nanotechnology's effects on health and the environment; and

WHEREAS: The City of Berkeley, California has amended the hazardous materials section of its Municipal Code in order to monitor those impacts; now therefore be it

ORDERED: That the City Manager be hereby requested to examine the nanotechnology ordinance for Berkeley, California and recommend an appropriate ordinance for Cambridge.

Cambridge thus far appears to have conducted little independent research or analysis of the issues presented by the Berkeley ordinance. In a recent *Boston Globe* article, a City Council

member is quoted as saying that the city wants to be "proactive" in assuring that businesses utilize nanotechnology safely. According to the councilmember, "The standard having been set by Berkeley, we will probably do something very similar to them."

This type of "proactive" approach presents the specter of a proliferation of local legislation regulating nanotechnology. Although the city councils in Berkeley and Cambridge both recognize the potential economic benefits of nanotechnology and express a desire not to stifle innovation in the area, their inclination toward enacting sweeping regulation of nanotechnology without careful study of the impacts that such regulation may have on business or researchers using nanotechnology, or of less intrusive regulations that might serve the same purposes, could in the end have that very effect.

If you have questions about this advisory, or would like to discuss it, please contact:

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