

Recommendations for a Municipal Health & Safety Policy for Nanomaterials

A Report to the Cambridge City Manager

July 2008

Submitted by:

Cambridge Nanomaterials Advisory Committee

Cambridge Public Health Department

CAMBRIDGE PUBLIC HEALTH DEPARTMENT



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Preface

In January 2007, the Cambridge City Council adopted the following policy order:

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

At the request of the City Manager, the Cambridge Public Health Department (CPHD) reviewed the Berkeley ordinance and related issues. In its written response to the City Manager, the public health department described the limited scientific consensus available to characterize the health risks posed by engineered nanoscale materials. Prior to making any regulatory or policy recommendations, the department proposed that an advisory committee be established so that city decision makers could learn more about the potential impact of the nanotechnology sector on public health and the impact of regulations on research and manufacturing. The proposed advisory committee would include experts in the field, as well as representatives from the universities, the community, and the nanotechnology manufacturing, research, and consulting sectors.

In summer 2007, the City Manager convened the Cambridge Nanomaterials Advisory Committee, which was charged with developing recommendations for oversight of local nanotechnology activities to protect human health. On behalf of the City Manager, the public health department facilitated six monthly meetings of the committee through January 2008. The committee developed a series of recommendations, which are described in this report.

The Cambridge Public Health Department endorses these recommendations and is prepared to implement them in collaboration with other city departments and with institutions and companies that conduct nanoparticle research and manufacturing.

Executive Summary

The Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, recommends that the City of Cambridge take several positive steps to gain a better understanding of the nature and extent of nanotechnology-related activities now underway within the city, to encourage research institutions and firms within the growing nanotechnology sector to share and improve practices leading to safe management of engineered nanomaterials, and to improve community access to the best available health and safety information as it relates to consumer products containing engineered nanomaterials.

In recognition of the limited health effects data and the absence of a clear consensus on best practices and standards for engineered nanomaterials, the Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, **does not recommend** that the City Council enact a new ordinance regulating nanotechnology at this time.

The Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, **does recommend** that the City of Cambridge take the following steps:

- Establish an inventory of facilities that manufacture, handle, process, or store engineered nanoscale materials in the city, in cooperation with the Cambridge Fire Department and the Local Emergency Planning Committee.
- Offer technical assistance, in collaboration with academic and nanotechnology sector partners, to help firms and institutions evaluate their existing health and safety plans for limiting risk to workers involved in nanomaterials research and manufacturing.
- Offer up-to-date health information to residents on products containing nanomaterials and sponsor public outreach events.
- Track rapidly changing developments in research concerning possible health risks from various engineered nanoscale materials.
- Track the evolving status of regulations and best practices concerning engineered nanoscale materials among state and federal agencies, and international health and industry groups.
- Report back to City Council every other year on the changing regulatory and safety landscape as it relates to the manufacture, use, and investigation of nanomaterials.

Introduction

Nanotechnology is the art and science of manipulating matter at the molecular level to create new and unique materials and products.

Materials engineered at the nanoscale measure between 1 to 100 nanometers in at least one dimension (width or length). A nanometer is a billionth of a meter, which is larger than most atoms but smaller than most molecules. At this small size, materials can have different electrical, mechanical, and light-reflecting properties that can be harnessed to produce useful devices in areas as diverse as medicine, alternative energy, agriculture, and consumer goods. Nanoscale research and manufacturing is a small, but rapidly expanding sector in North America, Europe, Asia, and Australia. The City of Cambridge is home to dozens of scientific and medical research laboratories, as well as several industrial producers working with engineered nanoscale materials.

Researchers worldwide are currently investigating the use of nanotechnology to perform atom-by-atom assembly of specific molecules and to mimic self-assembly found in biological systems. Most applications of this research are either years or decades away from practical benefit. However, engineered nanoscale materials are already being incorporated into an array of industrial and consumer products, including cosmetics and personal care products, sunscreens, paints, coatings, sporting goods, stain-resistant clothing, and light emitting diodes used in computers and cell phones.¹ Today, more than 600 “nanoproducts” are on the market globally.²

Despite that these products are already commercially available, the effects of engineered nanoscale materials on human health and the environment are largely unknown. Some of the same properties that make nanoscale materials useful may also pose risks to people and the environment, under specific conditions. Two significant areas of concern are (1) risk to people who manufacture, process, or conduct research on engineered nanomaterials, or reside close to facilities where these activities take place and (2) risk to the general population and the environment. The first concern is the central focus of this report, although consumer education is addressed in the recommendations chapter.

Several government-funded laboratories are currently researching the toxicity and safety of nanoscale materials, and some cautionary procedures have been developed for the safe storage and handling of these materials. There is general consensus among toxicologists that further research is needed regarding the characterization, safety, and handling of various engineered nanoscale materials.

¹ Consumer products inventory, Project on Emerging Nanotechnologies, Woodrow Wilson Institute. Available at: www.nanotechproject.org/inventories/consumer.

² “New Nanotech Products Hitting the Market at the Rate of 3-4 Per Week,” Project on Emerging Nanotechnologies, Woodrow Wilson Institute, April 24, 2008. Available at: <http://www.nanotechproject.org>.

Information Gathering and Committee Deliberation

The Cambridge Nanomaterials Advisory Committee (NAC) was convened in summer 2007 to assist the public health department in reviewing options for local oversight of facilities that handle or process engineered nanoscale materials.

The 19-member committee included individuals with professional expertise in the legal, scientific, and public policy disciplines related to environmental, occupational, and public health. A number of committee members are either employed as materials scientists and have detailed knowledge of engineered nanoscale materials or work in the nanotechnology manufacturing sector. Four committee members are also Cambridge residents, and represented the interests of their fellow citizens in this effort.

Sam Lipson, director of environmental health for the Cambridge Public Health Department, facilitated all six meetings of the Cambridge Nanomaterials Advisory Committee, which were held between August 2007 and January 2008.

At these meetings, NAC members discussed the present state of scientific knowledge about occupational and environmental health risks from engineered nanoscale materials, various oversight approaches that Cambridge might consider, and existing and likely future actions by regulatory authorities in other cities and at the state, federal, and international levels. These discussions helped clarify complex safety issues, risk management frameworks, and current efforts to understand engineered nanoscale materials, their potential impacts on human health, and their fate in the environment.

The following presentations from NAC members and the discussions that ensued provided the knowledge base and conceptual framework for the report recommendations:

- *Nanotoxicology overview*
Dr. Chris Long, Gradient Corporation
- *Oversight of nanomaterials safety in an academic setting*
Marilyn Hallock, MIT (presented in brief; slides made available to committee)
- *Overview of existing EPA, OSHA, and FDA regulations with implications for nanomaterials*
John Monica, Porter-Wright (a Washington, D.C. law firm)
- *Overview of risk management frameworks that could be used to address nanomaterials*
Dr. Igor Linkov, US Army Engineer Research and Development Center and Carnegie-Mellon University

In addition, Captain Gerard Mahoney of the Cambridge Fire Department provided detail to NAC members about ongoing efforts by the Fire Department and the Local Emergency Planning Committee to gather and maintain a citywide inventory of hazardous chemicals found in high volume or presenting special hazards.

Findings

In developing its recommendations, the Nanomaterials Advisory Committee limited the scope of its discussion to the potential health effects of engineered nanoparticles on people who manufacture, process, or conduct research on engineered nanomaterials, or those who reside close to facilities where these activities take place. This constraint was placed on the committee by the public health department, and reflects the practical and historic role that local public health agencies have played in protection of individuals in their places of work and residence.

Larger regulatory questions pertaining to the impact of these materials on the environment and on consumers of nanomaterial-containing products need to be addressed at the state or federal level where such oversight responsibilities traditionally and appropriately sit. This does not preclude the City of Cambridge from helping to improve consumer access to updated information about the safety of nanotech products.

Overview of Nanotoxicology

Nanotoxicology is an emerging subdiscipline of toxicology that explores whether and to what extent nanomaterials may adversely impact human health and the environment. Until quite recently, the toxicological assessment of materials on this scale primarily focused on “ultrafine particles,” which include *naturally occurring nanoparticles* (e.g., volcanic ash) as well as *incidental nanoparticles* (e.g., diesel exhaust, welding fumes) generated as by-products of industrial and commercial processes.

In the past few years, however, some toxicologists have begun to focus on *engineered nanoparticles*, which are purposely manufactured or created for their desirable physical and chemical properties. Engineered nanoscale materials assume a variety of structural forms, from self-assembling nucleic acids and semiconducting alloys to ornate forms of pure-carbon structures that are produced in several distinct shapes. It is essential to note that various engineered nanoparticles can differ significantly from one another with regard to their physical and chemical properties, and thus are likely to differ significantly from one another in their toxic potential. Like any broad class of substances, it is expected that some engineered nanoparticles will be found to be relatively non-toxic, while others (including those having the same chemical composition as their less pernicious cousins) will be found to be of much greater toxicity.

A proper assessment of the potential risk to humans requires evaluating the likelihood that a significant exposure will occur when these materials or compounds are produced, processed, or used in an expected manner. A responsible risk management process must be tailored to each worksite to understand the potential health risks that may be

present at that location. This “exposure assessment,” which is critical to the total estimation of risk, is quite specific to each situation and cannot be evaluated generically.

What Is Known About the Potential Health Effects of Engineered Nanoparticles

The examination of potential health risks from exposure to newly developed engineered nanoscale materials requires researchers to stretch beyond existing toxicology models and published data. Despite concerns raised by individuals (both scientists and non-scientists), the few studies that have been conducted specifically with engineered nanoscale materials do not yet suggest a clear pattern of harm. Some evidence of biological response or elevated reactivity has been presented, but it is not appropriate to use these narrow experimental observations alone to support a conclusion that such materials and products pose a threat under real-world conditions.

One related area of investigation concerns the toxicological effects of “ultrafine” particles. These are the nanoscale soot particles commonly found in exhaust from combustion processes, such as motor vehicle emissions, chimney smoke, and cooking fumes. Over the past three decades, research has shown there are several distinct types of damage to the human body that can occur when very small particles are inhaled at elevated concentrations. Studies indicate that some very small particles may gain entry to areas of the lung that are physically impossible for larger particles to reach and may then fail to be taken away (or cleared) during exhalation.

While engineered nanoparticles, such as carbon nanotubes, may share the nanoscale size with combustion-generated ultrafines, studies that associate chronic respiratory and cardiac problems to combustion-related particle exposures are assessing exposures to heterogeneous particles (comprised of organic compounds, metals, and other impurities) and hazardous gases that are simply not present in engineered nanoscale materials. Despite these differences, many valuable evaluation methods and principles describing transport (movement into and through the body) derived from this body of work have contributed to the study of nanotoxicology.

Although research is ongoing, there are a few important observations about engineered nanomaterials that can be found in the existing toxicological literature:

1. There is emerging evidence that biological effects observed in some studies are tied to various properties, including size, surface area, shape, surface chemistry, and electric charge of nanoscale particles. Some nanoscale particles that do not have special surface charges or reactive sites have been found to elicit inflammation at lower concentrations than would be expected with similar materials produced in larger dimensions (e.g. bulk graphite vs. carbon nanotubes). This has led to the observation that *total surface area* can sometimes be a better predictor of toxicity with certain classes of nanomaterials than mass concentration.

2. Some nanoscale materials appear to be associated with cellular oxidative stress (free radical mechanisms) once inside a cell. This process results in the release of unstable forms of charged molecules and is tied to genetic damage and cellular dysfunction. While this insight may become important in understanding the precise molecular mechanism of harm, it will not help scientists predict the likelihood of these materials finding their way from the place of initial contact into the bloodstream and then inside certain cells.
3. Important questions remain about the ability of inhaled nanoscale materials to be transported into the bloodstream and then to specific organs, or for nanoscale materials to penetrate the skin directly. Specific concerns have been raised about the possibility that engineered nanoparticles, like other nano-sized particles such as viruses, welding fumes, and diesel exhaust particulates, may be able to *translocate* directly into the bloodstream from the surface of the skin or along the olfactory nerve into the brain. There is only limited evidence that these uptake routes may be of potential significance for humans, and some evidence that direct translocation through the skin is not taking place.
4. It is essential not to presume that effects exhibited by “parent” materials (large-scale) can be extrapolated to the effects of the derived nanoscale equivalent (e.g. engineered nano-gold vs. simple gold dust). Efforts to predict nanoscale effects from existing toxicology data have been found to be less than useful in many cases.

Gaps in Knowledge About Health Effects of Engineered Nanoparticles

While ultrafine particle studies, along with earlier toxicological and clinical investigations, have laid the foundation for the nascent field of nanotoxicology, there are some fundamental questions about the impact of engineered nanoparticles on human health that earlier research did not resolve, such as:

- Can human exposures to engineered nanomaterials be prevented? If not, what is a safe threshold for exposure and what are the likely exposure levels that might be encountered by workers, researchers, and consumers?
- How are engineered nanoparticles taken up by the human body and how are they metabolized? Do they reach organs and tissues that larger, less reactive particles are not able to reach? Do they interfere with cellular signaling in consequential ways? Does the immune system treat materials on that scale differently?
- Are there chronic (long-term) health effects associated with exposure to engineered nanoparticles that cannot be evaluated with acute (short-term) and subacute (medium-term) studies? How can long-term effects be assessed without allowing people to be exposed to uncertain risks?

- Are there meaningful differences between the health effects of *engineered* nanoscale materials and those of *naturally occurring* or *incidental* materials with similar chemical composition? If there are different risks posed by engineered nanomaterials, then these materials must be evaluated separately and researchers cannot rely on toxicity values and mechanisms identified in previous studies.
- How do physical, chemical, and electrostatic forces alter the transport dynamics, physical separation, and surface charge of these materials after they are released during processing or manufacturing? How can experimental conditions be defined and controlled so that health effects studies are measuring exposure to discrete nanoscale materials rather than larger clumps of material likely to form over time?
- What is the probability (or risk) that a given individual will experience adverse health effects after being exposed to engineered nanoparticles for a limited period of time? What latent (or delayed) health risks might emerge years after the exposure has ended?

Studies addressing these questions may take many years to complete because it is difficult to rely on experimental controls and conditions traditionally employed in toxicology. The nanomaterials and nanoparticles that are the focus of these studies are derived from previously studied materials and compounds. But much of the complexity underlying the questions posed in this section stems from the fact that researchers are trying to identify hazards that are tied to the special properties exhibited by these derivatives. This requires a deeper understanding of how these materials and compounds differ from their “parent” materials and whether new tools need to be developed to observe these effects.

Risk Management

At present, regulatory agencies, industry groups, and health organizations at the state, national, and international levels are considering how to regulate or monitor possible health risks from engineered nanoscale materials using a full life-cycle (cradle-to-grave) assessment approach. It becomes a great practical challenge to establish an evidence-based risk management framework for the safe production, manipulation, and disposal of engineered nanoscale materials given the large number of questions that remain unresolved.

It is worth noting that regulatory agencies, manufacturers, and academic institutions in the U.S. and Europe have already taken the lead in incorporating a precautionary approach (avoidance of exposure) into a risk management framework to manage persistent uncertainties associated with many nanomaterials. Several creative frameworks have been developed that balance existing technical knowledge, expert judgment, and the use of precautionary policies in the face of larger gaps in knowledge. A responsible framework for managing risk in the face of basic uncertainties must

balance the value of the enterprise or research against the cost of taking protective precautionary measures that meet the standards of the company or institution and the community.

Here in Cambridge, the facilities and institutions most actively engaged in nanotechnology research and manufacturing (all of whom participated on the Nanomaterials Advisory Committee) already have highly protective procedures in place. What remains unclear is whether similar practices are being observed at all sites in the city where nanoscale materials are being handled in significant quantities.

Oversight

For any public agency considering regulations, evidence-based safety standards derived from a well-constructed risk framework are essential for meeting the public's expectation that government will provide reasonable assurance to workers and residents. Specific risk-based standards will also help establish credibility in the nanotechnology sector and delineate clear and reasonable expectations for the regulated community. As this technology becomes commonplace it will be important to identify, quantify, and avoid (when feasible) potential health risks. At this time, however, widely accepted standards are not available.

The Cambridge Public Health Department believes that inaction is not good public health policy in the face of persistent gaps in health effects data and uncertainty about how engineered nanoscale materials are being managed by firms not participating in this advisory committee process. In the absence of exposure standards and minimum safety practices, the Cambridge Public Health Department and the Nanomaterials Advisory Committee have concluded that active and constructive collaboration with firms and institutions in Cambridge that currently manufacture, process, or conduct research on engineered nanoscale materials is the most reasonable and effective strategy **at this time.**

This cooperation should be offered in the form of an elective review of risk management practices. Collection of data on the manufacture and use of nanoscale materials should be **strongly** encouraged, with appropriate assurances offered that safety and proprietary information gathered by the city will be protected under state law. Through this collaborative effort, employers would be encouraged to develop and implement precautionary procedures aimed at minimizing exposures to workers and releases to the environment. Such an effort to evaluate and share best health and safety practices would serve to improve the safety culture at Cambridge facilities and laboratories. Once policies, standards and safety regulations have been developed for nanomaterials by federal, state, academic, and industry partners, Cambridge will then be able to recognize existing gaps that could be addressed with enhanced local oversight.

Recommendations

The Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, recommends that the City of Cambridge take several positive steps to gain a better understanding of the nature and extent of nanotechnology-related activities now underway within the city, to encourage research institutions and firms within the growing nanotechnology sector to share and improve practices leading to safe management of engineered nanomaterials, and to improve community access to the best available health and safety information as it relates to consumer products containing engineered nanomaterials.

At this time, in recognition of the limited health effects data and the absence of a clear consensus on best practices and standards for these engineered nanomaterials, the Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, **does not recommend** that the City Council enact a new ordinance regulating nanotechnology at this time.

The Cambridge Public Health Department, in collaboration with the Cambridge Nanomaterials Advisory Committee, **does recommend** that the City of Cambridge take the following steps:

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- Offer technical assistance, in collaboration with academic and nanotechnology partners, to help firms and institutions evaluate their existing health and safety plans for limiting risk to workers involved in nanomaterials research and manufacturing.
- Offer up-to-date health information to residents on products containing nanomaterials and sponsor public outreach events.
- Track rapidly changing developments in research concerning possible health risks from various engineered nanoscale materials.
- Track the evolving status of regulations and best practices concerning engineered nanoscale materials among state and federal agencies, and international health and industry groups.
- Report back to City Council every other year on the changing regulatory and safety landscape as it relates to the manufacture, use, and investigation of nanomaterials.

The following section describes these recommendations in greater detail.

- 1. The City of Cambridge should develop an inventory of commercial, industrial, and research facilities in Cambridge that manufacture, process, handle, or store engineered nanoscale materials (excluding nanomaterial-containing consumer products).**

Current knowledge about possible human health effects from engineered nanoscale materials in Cambridge is incomplete. Basic information should be collected from each facility, and should include sufficient detail to identify potential risks, exposures, and exposure mitigation strategies.

To minimize the reporting burden on facilities engaged in nanotechnology research processing or manufacturing, a survey should be developed in cooperation with the Cambridge Fire Department and the Cambridge Local Emergency Planning Committee (LEPC) as part of their ongoing emergency planning and data collection efforts. The survey should be sent to the fire department's list of laboratories (approximately 75 facilities), selected SARA Tier II facilities (approximately 35 facilities), and facilities with flammables permits where it is thought that engineered nanoscale materials may be present (a currently unknown subset of approximately 700 facilities with flammables permits).

The advisory committee and the public health department envision the survey as the starting point of an effort to reach out to and learn more about Cambridge organizations and firms working with or manufacturing engineered nanoscale materials. Lessons learned from the information gathered through this survey will be incorporated into further efforts to provide technical assistance to encourage best practices for health and safety. Information collected through the survey and other technical assistance activities are strictly protected under state public records laws as confidential business information (CBI).

- 2. The City of Cambridge should implement a *voluntary* engineered nanoscale materials technical assistance program.**

The public health and fire departments should establish a voluntary working relationship with nanomaterials researchers and manufacturers to (1) share information about scientific and regulatory developments and (2) develop best management practices intended to minimize occupational and environmental health and safety concerns.

The City should offer positive acknowledgement for facilities willing to participate in this effort if such recognition is desired. Development of this technical assistance resource should take advantage of existing efforts at identifying best management practices for health and safety in this sector. Organizations that have supported this policy review process and who have indicated an interest in supporting a "best practices" initiative in Cambridge include the Massachusetts

Institute of Technology, Harvard University, National Science Foundation-funded programs at Northeastern University and the University of Massachusetts at Lowell, the Project on Emerging Nanotechnologies at the Woodrow Wilson Center (Washington, D.C.), and the Toxic Use Reduction Institute.

3. The City of Cambridge should increase efforts to educate the public about engineered nanoscale materials.

The committee recommends two approaches for enhancing public knowledge about engineered nanoscale materials:

- a. Post basic information about engineered nanoscale materials on the Cambridge Public Health Department website. The web pages should include links to other well-vetted governmental and well-regarded Internet sites with information about nanomaterials in the workplace, the environment, and consumer products.
- b. Sponsor or co-sponsor a public forum to discuss the best strategies for informing residents about commercially available products that contain engineered nanoscale materials. The first such public forum in Cambridge on public perceptions and information needs will be co-hosted by the Museum of Science on May 22, 2008 at MIT. Feedback from this public event will help guide the public health department in its future efforts to provide public information about products containing nanoscale materials.

4. The City should instruct the public health department to provide a report to the City Council summarizing progress with the three recommendations stated above. This report should also provide an update on major changes in the scientific consensus on health risks and state or federal regulatory oversight regarding engineered nanoscale materials. This report should be presented to the City Council every two years.

This report should include a brief review of both scientific and regulatory developments relevant to the safe manufacture, handling, and use of engineered nanoscale materials in Cambridge; and an update on regulatory and consensus-based standards developed to promote safety of engineered nanoscale materials.

In the event that new state or federal regulations are deemed insufficient to address the understood risks in this community, a review of local oversight options would be recommended.

In the event that new, previously unrecognized risks are identified, with or without state or federal action, a review of local oversight options would also be recommended.

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*Copies of these materials can be obtained by contacting
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