STEP White Paper Competition
March 11, 2007

The Berkeley City Ordinance on Nanotechnology:
Shortcomings, improvements, and implications for risk governance

Javiera Barandiaran

Executive Summary

Nanotechnology is focusing increasing research funds and appearing in a growing number of consumer products. In addition to the benefits, nanotechnology also poses certain risks for human health and the environment. For this reason, among others, nanotechnology requires a regulatory framework. What this framework should be is the object of intense debate among the science, business and government communities that will have consequences both for nanotechnology governance and general risk governance.

In this context Berkeley City Council became the first government entity in the United States to approve a specific ordinance requiring the reporting of nanomaterials used in local laboratories. This ordinance has been criticized for the burden it places on researchers and for the inadequacy of the information it collects. This paper proposes to conduct an evaluation of this ordinance with the specific objective of proposing improvements in the format used to collect information and the categories of information collected. In this process, issues related to risk classification and governance will be addressed.

The Berkeley City Ordinance on Nanotechnology: Shortcomings, improvements, and implications for risk governance

The impact of nanotechnology on research and the economy has grown substantially over the past years

In defining nanotechnology, the emphasis lies not on the scale or size, but on the potential to apply size-dependent qualities for an innovative function. That is, on leveraging the effects of scale for some new, useful purpose. Basing itself on the definition developed by the US government's 2001 National Nanotechnology Initiative (NNI), the EPA defines nanotechnology as:

> …research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred nanometers in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale (EPA 2007).

In February 2007 the EPA published its second Nanotechnology White Paper, laying out a list of priorities for toxicology research and a map of relevant government agencies which should participate in this process. The EPA states that nanotechnology research and development spending for 2006 is estimated at $9 million globally (EPA 2007, citing Lux Research). Furthermore, the National Science Foundation invested in 2006 $5.4 million just on ethical, legal and social research and education related to nanotechnology (Sherman 2006), while the Woodrow Wilson Center has created a Consumer Products Inventory that currently catalogues 200+ consumer products which use nanotechnology in some way. Beyond some of the controversy which surrounds nanotechnology, these efforts attest to its importance on the research agenda and its growing economic impact.

Nanotechnology could bring important improvements to currently available technologies and applications in areas such as environmental remediation, sensors, manufacturing, energy production and delivery, drug delivery, optics, and many others (EPA 2007, Maynard 2006, Roco 2005). On the other hand, it is increasingly accepted that nanotechnology may also pose some risks. These are primarily of two types, environmental and human health hazards. While some toxicological research has been conducted, a general consensus exists that these efforts need to be greatly increased (EPA 2007, Maynard 2006, Roco 2005, Renn 2005, Sherman 2006). Drawing on the literature review conducted by the EPA, some examples of research that has found nanomaterials to pose hazards are:

- Nanoscale quantum dots have been found to absorb into the skin and disperse into other tissue. Also, varieties of quantum dots, used for example in photovoltaic cells, are different and may require specific toxicology tests.
- Studies on dendrimers, used for drug delivery, show that the surface charge of a nanoparticle can alter the integrity and permeability of the blood-brain barrier.
- Oberdorster (2005) has observed a range of potential human health hazards. In particular, he finds that nanoparticles can: (i) when inhaled, reach "potentially sensitive target sites" (for example, bone marrow, lymph nodes, spleen, and heart) and can access the central nervous system and ganglia, and (ii) penetrate the skin and can absorb into lymphatic channels. Other

studies on the inhalation of nanoparticles have found that the accumulation of materials in human lungs varies with the presence of a pre-exisiting condition such as asthma.

- Carbon nanotubes have been found to be toxic for the lungs, although this effect appears to depend on how the tubes are manufactured, coatings used, among other factors.
- In the environment, nanomaterials appear to have a tendency to cross cell membrane barriers and accumulate, though some mitigating effects may exist. Studies have been undertaken with fish, but much more research is needed.
- Research on C_{60} fullerenes finds that they induce oxidative stress and may negatively effect the structure, stability and biological functions of DNA.
- Some research into nanomaterials and soil finds that these are more toxic on a mass-based exposure metric, while some nanomaterials show unique toxicity not explained by size. Furthermore, it is known that uptake in soil, plants and water is different. Toxicity is further complicated by the coatings used on some nanomaterials, which may be reactive even if no uptake is observed.

From the research on toxicity conducted thus far, two key patterns emerge. First, nanomaterials need to be researched for their toxicity, and lack of evidence should not be interpreted as 'lack of hazard' (Renn 2006, Roco 2006, Maynard 2006). Second, chemical composition, weight and mass do not capture all the relevant variables that effect the potential for toxicity of nanomaterials. Many other factors need to be considered, such as surface-to-mass ratio, surface chemistry (coating), in vivo surface modifications, among others (EPA 2007, Maynard 2006, Davies 2006, Oberdorster 2005-1 and 2005-2, Dunphy-Guzman 2006).

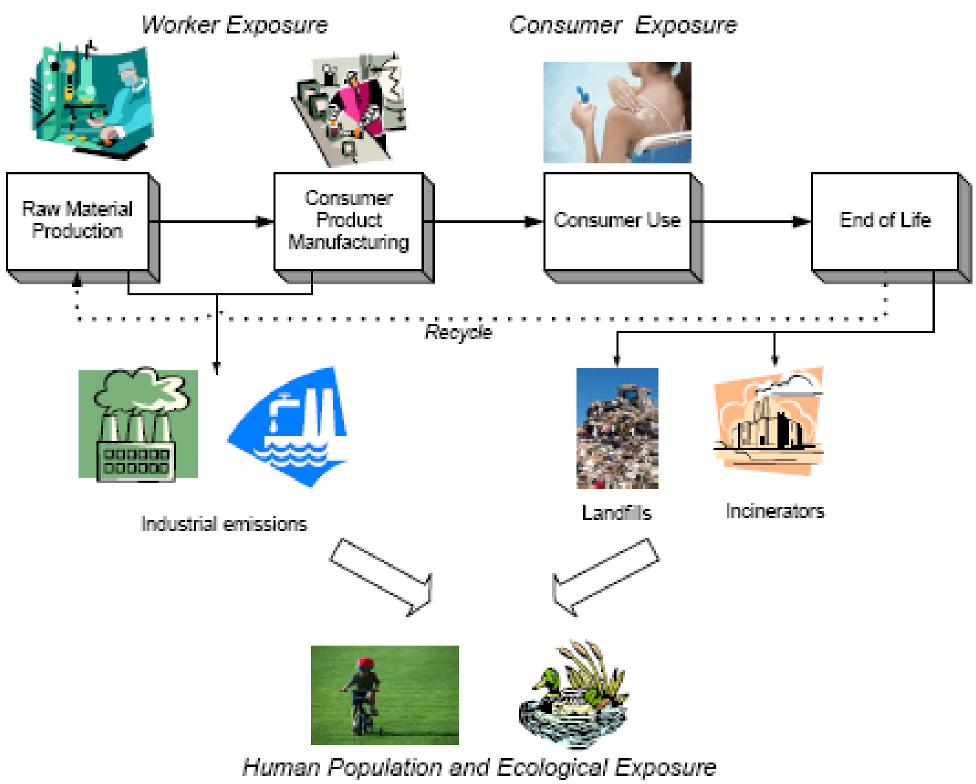

Figure 1: Life cycle perspective to Risk Assessment (EPA 2007)

Regulating nanotechnology is challenging because of the complexity of the field and the diversity of potential applications

Many firms, industries and governments are investing in nanotechnology. To both facilitate the transfer of this technology from the laboratory to the market and ensure that this process adequately addresses the potential hazards of nanomaterials, clear regulation is required in order to ensure labeling and classifying standards (EPA 2007, Davies 2006, Maynard 2006). These are important for the exercise and enforcement of intellectual property and business development rights, for successful and truthful marketing strategies, and for adequate monitoring of potentially toxic substances. Beyond the definition of nanotechnology, its regulation tends to focus on human engineered rather than naturally occurring nanomaterials.

For example, the Woodrow Wilson Center's Consumer Products Inventory relies on manufacturers' or some other sources' claims about whether a product uses nanotechnology (CPI website). In the absence of clear standards and definitions about what 'counts' as nanotechnology, it is difficult for businesses, government, researchers and consumers to manage information about nanotechnology, to make linkages across different research or to plan for different risk scenarios (Renn 2005). Furthermore, this ambiguity creates the perception that nanotechnology is monolithic or homogenous, when this is an area of research that comprises a vast range of materials, processes and applications. From the point of view of public opinion, the current situation can foment feelings of distrust in government institutions, seen to be responsible for regulating toxic substances, that can be projected on the whole of nanotechnology rather than on the specific materials or applications that pose hazards (Renn 2005). Negative views or feelings are difficult to change once they become rooted in the collective mentality.

There is growing agreement that the current regulatory framework inadequately addresses the potential hazards of nanotechnology (EPA 2007, Roco 2006, Davies 2006). Currently nanotechnology is regulated within existing legal frameworks, principally the Toxic Subtances Control Act (TCSA), the Occupational Safety and Health Act (OSHA), the Food and Drug Administration (FDA) and a collection of other laws ranging from the FIFRA act regulating pesticides to pollution control legislation. Some sectors, however, support the creation of a specific regulatory framework for nanotechnology because of the importance of structure in determining the effects of nanomaterials (Davies 2006).

Berkeley City Council: the first to specifically regulate nanotechnology

In this context of uncertainty, Berkeley City Council has taken the lead in regulating nanotechnology by adopting a manufactured nanoscale material disclosure ordinance (Berkeley City Council 2006). This ordinance, the first of its kind in the US, is part of the hazardous materials business plan HMBP requirements and aims to provide a flexible mechanism by which local groups using nanotechnology must inform the City Council of the potential toxicity of the materials being used and what measures they have taken to minimize exposure and hazard.

As the first of its kind, the Berkeley ordinance is well placed to serve as a model for regulation. The city council of Cambridge, Massachusetts, has already expressed interest in mimicking this ordinance (Small Times 2007). Furthermore, the Berkeley ordinance should have the effect of gathering a large amount of specific information on nanomaterials in what is possibly one of the cities with the highest concentrations of nanoscale research being conducted (even if Lawrence Berkeley Lab, and the Molecular Foundry, are exempt. MSNBC 2006). As a first attempt, the categories used by Berkeley to classify this information may have important consequences for how nanomaterials are classified in the future and for how the policy community thinks about nanomaterials.

How elements are classified –"distinguishing like from unlike; deciding what counts as likeness or unlikeness"- has profound implications for how "knowledge becomes an orderly affair" (Bloor 1982 p. 267). By imposing order on knowledge, networks of knowledge are created that set the standard of what constitutes 'true' knowledge and what remains on the margins of accepted practice. How classification systems in science parallel social or political processes has been well described in the science and technology studies (STS) literature (Jasanoff 2005, Nowotny 2001). Science and technology transform natural phenomena into socially useful understandings and applications that, by being social, necessarily respond to some human-defined goals and interests. In so far as these interests respond to social or political views of what is desirable –and worth financing with public money- the order imposed on scientific knowledge will reflect collective conceptions of what is correct, necessary or good rather than purely scientific criteria (Bloor 1982). This is a complex process that can have profound implications for the research agenda and public policy, among other areas.

From this perspective, it is important to consider some of the many criticisms of the Berkeley ordinance. The ordinance sets up a reporting system rather than a control mechanism. While this is an important first step given that toxicity tends to go unmonitored unless there is a requirement to do so, the ordinance currently lacks legal teeth and administrative power to prove very useful. Among the criticisms leveled at the ordinance, the following are most relevant to the purposes of this research proposal[1]:

1) The use of an 'open format' rather than a closed, pre-defined questionnaire will lead to the collection of a large amount of information that is difficult to analyze or process, especially for a city government with limited human and financial resources. This format will negatively effect the process of linking specific nanomaterials to particular characteristics that, in conjunction, pose health or ecological hazards. Furthermore, the lack of clear variables to be recorded hinders efforts at comparative research or of cross-referencing different data bases or other regulations.
2) The type of information required by the ordinance fails to capture some key characteristics of nanomaterials considered to be important in their potential toxicity. Although the identification of the exact variables that should be recorded is difficult given the current gaps in knowledge on the toxicity of nanomaterials, some qualities do appear to be very important and specific to these types of particles: surface to mass ratio, coatings, combinations of nanomaterials, etc.
3) The ordinance is burdensome not only for the City Council to manage, but also for firms and researchers to respond to. Its existence may provide an incentive for companies, especially small start ups for which the costs of compliance are relatively larger, to relocate to neighboring municipalities.

[1] Identification of these concerns arose in conversation with Thom Opal, EH&S Specialist at UCB, and Philip Maynard, Lab Safety Specialist at UCB, at the meetings of the Roundtable on the Environmental Risks of Nanotechnology, organized in Spring 2007 by the Berkeley Institute of the Environment.

On the positive side, the Berkeley ordinance provides a powerful test case for the regulation of nanotechnology and introduces the classification of nanomaterials according to “control bands”. A common procedure in European regulation, control bands are relatively underused in the US. However, given the large amount of relevant variables on which nanomaterials need to be evaluated, the development of broader categories of ‘classes’ of materials and ‘bands’ of risk can help reduce and simplify the number of factors which should be recorded. The EPA Nanotechnology White Paper, for example, also takes some initial steps in this direction by classifying nanomaterials into four larger categories (carbon-based materials, metal-based materials, dendrimers and composites).

Evaluating and improving the Berkeley City Ordinance

The objective of this paper is to propose an evaluation of the Berkeley ordinance, in an attempt to provide partial answers to the following questions:

1) How does the ordinance compare to existing, analogous frameworks such as the Toxics Release Inventory Act (TRI)? The TRI tracks over 600 substances considered to be toxic in an effort to provide ‘right to know’ legislation. This framework could provide a model against which to evaluate the Berkeley ordinance, and provide clues as to what information gathering format is best suited for this kind of endeavor.
2) What information is superfluous and which vital for tracking nanomaterials in the current context of uncertainty? In particular, this research would aim to propose a set of variables that should be collected and the format in which they should be collected and recorded.
3) Finally, which institutions are or should be involved in the debate about reporting? To increase both its quality and impact, the ordinance would benefit from greater inputs from relevant government, science and business organizations. This would include an evaluation of the adequacy of the concept of control bands, an exploration of the feasibility of different reporting mechanisms, and a discussion of how to characterize risks (acceptable, tolerable, intolerable or undefined) and how to respond (risk-benefit analysis, risk-informed, precaution-based or discourse-based approaches) (Renn 2006).

As researchers in Berkeley, we are in a unique position to evaluate this ordinance with ready access to many of the personalities involved in its crafting. Through the Roundtable on the Environmental Risks of Nanotechnology and the Berkeley Nanotechnology Club, I have contacted experts in this area, including Thom Opal and Philip Maynard who work in Laboratory Safety at UCB and Nabil Al-Hadithy of Berkeley City Council, among others. Both forums provide the opportunity to involve more experts in this research project. Depending on the time frame and availability of funds, this project could include a series of interviews with experts in this process to complement an analysis of the documents and literature.

This research project seeks to address questions that are of direct interest to the current policy debate on how to regulate nanotechnology, and also of interest to academic researchers beginning to work in a new field where the literature is yet unconsolidated. The newness of this ordinance poses both advantages and challenges: on the one hand, many aspects of the conditions which led to its drafting and approval are still difficult to analyze –interest groups are as yet relatively unformed- while on the other, the possibility of studying the creation of policy as it occurs offers special opportunities for influencing its outcome.

Bibliography

Berkeley City Council. (2006) "Introduction to Manufactured Nanoscale Material Health and Safety Disclosure for the Reporting Period of June 1, 2007-June 2, 2008". Planning and Development Department, Toxics Management Division. Document provided by the Berkeley City Council.

Bloor, David. (1982) *Durkehim and Mauss Revisited: Classification and the Sociology of Knowledge*. Studies in the History and Philosophy of Science, 13, 4: 267-297.

Davies, Clarence. (2006) *Managing the Risks of Nanotechnologies*. The Woodrow Wilson Center for Scholars.

Dunphy-Guzman, Katherine, M. Taylor and J. Banfield. (2006) *Environmental Risks of Nanotechnology: National Nanotechnology Initiative Funding, 2000-04*. Environmental Science and Technology, 40: 1401-1407.

Environmental Protection Agency (EPA). (2007) *Nanotechnology White Paper.*

Guston, David H. and Daniel Sarewitz. (2002) *Real-time Technology Assessment.* Technology in Society, 24: 93–109.

Jasanoff, S. ed. (2005) *States of Knowledge: The Co-production of Science and Social Order.* Chapter 2 in Ordering Knowledge, Ordering Society. London, Routledge: 13-45.

Maynard, Andrew, et al. (2006) *Safe Handling of Nanotechnology*. Nature, Vol 444, 16: 267-69.

Maynard, Philip (2007). Private conversation.

MSNBC (Dec 12, 2006), http://www.msnbc.msn.com/id/16167181/

Nowotny, H., P. Scott and M. Gibbons. (2001) *Re-thinking Science: Knowledge and the Public in an Age of Uncertainty.* Chapter 3 in The Co-Evolution of Society and Science. Cambridge, Polity: 30-49.

Oberdörster, Günter, et al. (2005-1) *Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy*. BioMed Central.

Oberdorster G, Oberdorster E, Oberdorster J. (2005-2) *Nanotoxicology: an Emerging Discipline Evolving from Studies of Ultrafine Particles*. Environmental Health Perspectives, 113 (7): 823-39.

Opal, Thomm (2007). Private conversation. HIS TITLE.

Sherman, Brad. (2006) *Environmental and Safety Impacts of Nanotechnology: What Research is Needed?*. US House of Representatives, Hearing.

Renn, O. and M.C. Roco. (2006) *Nanotechnology and the Need for Risk Governance*. Journal of Nanoparticle Research, 8: 153–191

Roco, M.C. (2005) *The Emergence and Policy Implications of Converging New Technologies Integrated from the Nanoscale*. Journal of Nanoparticle Research 7: 129–143

Small Times. (Jan 26, 2007), http://www.smalltimes.com/articles/article_display.cfm?Section=ARCHI&C=Mater&ARTICLE_ID=283218&KEYWORDS=regulation&p=109

Slovic, Paul et al. (2004) *Risk as Analysis and Risk as Feelings: some thoughts about Affect, Reason, Risk and Rationality*. Risk Analysis, Vol 24, No 2

Woodrow Wilson Center Consumer Products Inventory (CPI), http://www.nanotechproject.org/index.php?id=44