A Nanotechnology Policy Framework for California

A. Wise [*], T. Woodruff[*]

[*]Program on Reproductive Health and the Environment,
University of California-San Francisco, CA, USA,
wisea@obgyn.ucsf.edu, woodrufft@obgyn.ucsf.edu

ABSTRACT

The goal of this project is to address the growing concern about the potential health risks posed by manufactured nanotechnology materials and products. The main outcome of this project will take the form of a Nanotechnology Policy Framework document for the State of California which provides an overview of nanotechnology materials and their potential exposures and health risks and proposes policy options for addressing potential hazards and risks from nanotechnology. Nanotechnology materials present new challenges to the policy and risk assessment process because of their unique properties, leaving them no obvious fit within current regulatory and policy guidance and frameworks. Many reports have already been written on this subject, with a general theme emerging of "more information on exposure and toxicity is needed", and calling for some sort of information-gathering mechanism, be it voluntary or required. This document will draw upon these studies, to avoid redundancy and will expand on their conclusions to determine the best course of action for California[1].

Keywords: nanotechnology, environmental health, toxicity, policy, exposure

1 INTRODUCTION

While the benefits of nanotechnology are widely publicized, the discussion of the potential effects of their widespread use in the consumer and industrial products is arguably lacking. The large data gaps that exist on use, exposure and health effects create a difficult situation for policy makers and the general public alike. The unique material properties their size affords them also makes them highly mobile when interacting with the environment or humans. It has been shown that nanomaterials can enter the human body through several ports and can actually translocate through the bloodstream to other vital organs [1], so it will be important to characterize both transport properties and exposures to understand their potential toxicity.

California has three of the top five leading "Nano Metro" centers in the United States: San Jose, San Francisco and Oakland (can be seen in Figure 1). The other two—Boston and Middlesex-Essex—are in Massachusetts[2]. These Nano centers include nanotech companies, universities, research laboratories, and organizations. As the State of California is clearly emerging as the domestic frontrunner in nanotechnology competition, it will inevitably be used as a model for future investments and developments in this field. This will require careful thinking and planning on a highly interdisciplinary level to coordinate effective risk management mechanisms while allowing for the economic and societal benefits nanomaterials can bring. The lack of resources, both monetary and human resources, to implement new structure or programs into government bodies or regulation is a constraint mentioned in almost all other reports on this subject. Creative solutions will need to be crafted that include data and information sharing, collaboration and economizing.

The framework document will draw upon more in-depth discussions of the field and the necessary policy needs to adequately protect human health. We will highlight and summarize major findings in toxicology and environmental health research, attempt to characterize and prioritize human exposures to nanoproducts, including what we might learn from past chemical exposure situations. We will also consider current regulatory frameworks, both at the state and federal level, and offer some concrete suggestions for new risk management strategies for nanomaterials in the policy arena. Here, we present the initial findings of this work, as the project is still in progress at press time of this article, with a proposed finishing date of fall 2009. In this paper, we will be generally outlining the framework document, and salient points identified to date.

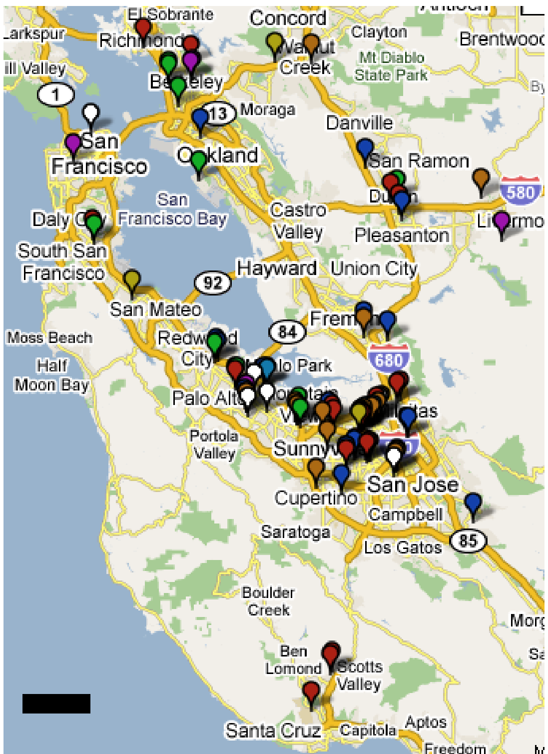
2 THE CURRENT STATE OF NANOTECHNOLOGY

California is the leading state for nanotechnology industry and research[2]. In the United States, the National Science Foundation forecasts up to 2 million jobs will be

[1] This work is being funded by the State of California Environmental Protection Agency's Office of Health Hazard Assessment.

created in the next 15 years utilizing nanotechnology. It is estimated that approximately 200,000 jobs in nanotechnology will be created in the State of California by 2020. Figure 1 illustrates the number of nanotechnology groups just in the San Francisco Bay Area,--other parts of California, especially in the Los Angeles area have high densities of research and corporate entities in this field.

Figure 1 Map of nanotechnology in San Francisco Bay Area with sector-specific locations of academic, government and private industry. **Map courtesy of Woodrow Wilson Center's Project on Emerging Nanotechnologies. Scale bar = 10 miles**



Electronics Imaging and Microscopy
Energy and Environmental Applications
Medicine and Health Materials Organization
Tools and Instruments Academic & Gov't research

Outside of California and the United States, the estimated economic implications of nanotechnology are vast. It is estimated that by 2014, 15% of goods manufactured worldwide will contain nanotechnology[3]. Nationally and worldwide it is a fast-growing sector of the economy that holds promise to continue. A brief summary of the uses of nanotechnology can be seen in Table 1, including the estimated number of consumer products that contain nanomaterials. The large number of household and personal care products indicates a high possibility for human exposure and highlights the importance of addressing data gaps on toxicity.

Table 1 Summary of general uses of nanoparticles in products. The third column is the approximate number of products on the market as of August 2008 containing these materials worldwide, according to the Project on Emerging Nanotechnologies.

Category	Nanomaterial use	#
Electronics	Metallic and inorganic connections, separation membranes, display technologies, memory/storage	61
Household	Anti-bacterial coatings for food storage and preparation, baby products, anti-stain fabrics, cleaning supplies	213
Personal Care	Cosmetics, sunscreens, dietary supplements	204
Materials	Paints, coatings, material strength properties, sporting goods	156
Environmental	Sensors, filters, agricultural products	34
Medical	Drug delivery, isolated treatment, diagnostics and imaging, tissue regeneration	unknown

3 A SUMMARY OF REPORTS

As previously mentioned, many reports have already been written on nanotechnology and its impacts both by national government bodies and non-governmental organizations (NGOs). These reports include white papers[4], summaries of the current state of nanotechnology[5], the potential environmental impacts [6, 7], assessments of current and potential regulatory efforts[8-10], and other scientific reviews. A common theme emerges that more information and research is needed on exposure, human health effects, and other environmental interactions before we can make informed decisions on policy. While this is generally true, we will also take into consideration examples of "lessons learned" in the past from other chemical substances and situations to further our decisions.

Many of the reports that have been written on nanotechnology have overlapping themes and conclusions, which can be summarized in Table 2.

In addition to these reports on nanotechnology, a series of relevant reports from the National Academy of Science's National Research Council (NRC) have recently been released. Particularly addressing nanotechnology is *Review of Federal Strategy for Nanotechnology-related Environmental, Health and Safety Research.* This document outlines what a good strategy would look like and assesses if the government is prepared to fulfill these strategy goals. It concluded the federal government fell short in almost all the areas. It states the National

Nanotechnology Initiative (NNI) "does not have present a vision, contain a clear set of goals, have a plan of action for how the goals are to be achieved, or describe mechanisms to review and evaluate funded research and assess whether progress has been achieved"[10] In short, there is no clear set of strategy goals or even a coordinated research plan to address areas known to contain data gaps.

Table 2: A summary of main conclusions from recent government and non-government nanotechnology reports. Abbreviations: PEN: Project on Emerging Nanotechnologies, AUS: Australian government, EPA: U.S. Environmental Protection Agency, CAN: Canadian government, UK: United Kingdom government, NAS: U.S. National Academy of Science. See references [3-7, 10-12].

General Conclusion	Source of report
Existing regulations fall short and are "weak and inadequate" to deal with this, if they exist at all.	PEN, AUS, CAN, UK, NAS.
There exist large data gaps: toxicity, exposure routes, health effects, bioaccumulative properties, etc.	PEN, AUS, EPA, CAN, UK, NAS
There is a need for regulators to continue to research, monitor and identify specific causes for concern.	PEN, AUS, EPA, CAN, UK, NAS
There is a need for nano-specific research to fill data gaps	PEN, AUS, EPA, CAN, UK, NAS
Better coordination and communication is needed between agencies, governments, private industry and NGOs.	PEN, AUS, EPA, CAN, UK, NAS
New methods of risk assessment maybe needed, such as: Determining adverse biological outcomes due to exposure to certain types of materials Using predictive toxicology New laws or regulations	PEN, CAN, UK, NAS
Prioritization and standardization of methods will be critical.	CAN, UK

Other National Research Council reports that we will use to guide our recommendations for this project, include the *Advancing Risk Assessment*, and *Phthalates and Cumulative Risk Assessment,* and *Toxicity Testing in the 21st Century: A vision and a strategy.* These contain important observations about how to address data gaps in research, how to incorporate multiple chemicals exposure, highlight vulnerable sub-populations (i.e. pregnant women, children, & worker exposure) and ways to improve existing regulation.

4 CURRENT REGULATORY CONTEXT AND WHERE NANOTECH MIGHT FIT

In general, most nanomaterials are regulated under TSCA (or in some cases such as cosmetics under various FDA codes) and are cataloged with the same CAS# as the nanoparticle's main components in the bulk form. However, since nanomaterials are touted as being unique due to their size, it's becoming clear that other characteristics beyond the normal chemical components and physical properties will need to be used for safety determination. Indeed, in March 2009 the EPA will begin enforcing a decree that requires all manufacturers and importers of carbon nanotubes to notify the agency before releasing their products onto the market. Federal regulators also recently declared that they will soon demand tighter controls on nanoscale particles of titanium dioxide (used in paints, pigments and sunscreens) and alumina/silica, in recognition of the added health risks these ultrafine powders appear to pose compared to their larger particulate cousins.

On the state level, California is the first and only state to begin nano-specific information call-ins. In January, California's Department of Toxic Substances Control (DTSC) sent letters to the 27 companies and universities that it believes are manufacturing or importing carbon nanotubes, requesting information about production volumes, locations and materials used. Additionally, California passed a Green Chemistry Initiative in Dec. 2008, which will likely contain useful structure for safe nanotechnology innovation and some mechanism for listing and reporting toxic substances.

Internationally, Canada just implemented the first mandatory reporting requirement of physical, chemical and toxicological properties of nanoparticles for anyone who makes or imports more than 1kilogram per year. It will then use the data to make risk assessments and establish more specific regulations[13]. It seems some form of mandatory reporting will be necessary, as the EPA recently investigated the effectiveness of their voluntary reporting program in nanotechnology and concluded that very few companies participated and the data submitted was generally of poor quality [14].

Some of the largest hurdles to overcome for integrating nanotechnology into current regulatory structure include:

1. Shortcomings of regulations (there is no obvious fit for nanotechnology currently)
2. New approaches will be needed to address past experiences and incorporate new information
3. Limited monetary and human resources

4. Large data gaps on human exposure, health effects and toxicology
5. Lack of inter-agency collaboration and coordination.

Our recommendations will look at how to address each of these while considering the beneficial economic impacts, prioritizing human exposure scenarios and toxicities, suggest how to incorporate green chemistry principles to incentivize safe materials, and offer recommendations for new risk management strategies for nanomaterials in the policy arena.

REFERENCES

[1] A. Nemmar, et.al. *Am. J. Respir. Crit. Care Med.* **2001**, 164, 1665-1668.

[2] Project on Emerging Nanotechnologies *Nanotechnology Map*, Woodrow Wilson Center for International Scholars, **2008**.

[3] J. Davies, *EPA and Nanotechnology: Oversight for the 21st Century*, Vol. 9, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, **2007**, pp.76.

[4] US EPA *Nanotechnology White Paper*, Vol. 100/B-07/001, U.S. Environmental Protection Agency, Washington DC, **2007**, pp.120.

[5] Australia's New South Wales Standing Committee on State Development, *Nanotechnology in NSW Final Report,* Legislative Council, Sydney, **2008**, pp.204.

[6] UK, Royal Commission on Environmental Pollution *Novel Materials in the Environment: The case of nanotechnology,* London, **2008**, pp.147.

[7] J. Davies, *Managing the Effects of Nanotechnology,* Vol. 2, Project on Emerging Nanotechnologies, Woodrow Wilson Center for International Scholars, Washington DC, **2006**, pp.34.

[8] A. Maynard, *Nanotechnology: A Research Strategy for Addressing Risk,* Vol. 3, Project on Emerging Nanotechnologies, Woodrow Wilson Center for International Scholars, Washington DC, **2006**, pp.45.

[9] S. Keiner, *Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology*, Vol. 11, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington DC, **2008**, pp.58.

[10] National Academy of Science, *Review of Federal Strategy for Nanotechnology-Related Environmental, Health and Safety Research,* National Academies Press, Washington DC, **2008**, pp.80.

[11] J. Davies, *Nanotechnology Oversight: An Agenda for the New Administration*, Vol. 13, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Washington DC, **2008**, pp.39.

[12] Council of Canadian Academies, *Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale,* Expert Panel on Nanotechnology, Ottawa, **2008**, pp.133.

[13] K. Sanderson, *Nature*. **2009**, 457, 647-647.

[14] US EPA *Nanoscale Materials Stewardship Program Interim Report*, Office of Pollution Prevention and Toxics, Washington DC, **2009**, pp. 38.