MESM 2010 Group Project Proposal:
EVALUATING RECOMMENDED AND REPORTED PRACTICES IN
NANOMATERIALS ENVIRONMENTAL HEALTH AND SAFETY

PROPOSERS: Adeyemi Adeleye and Sudhir Paladugu, MESM Class of 2011; Patricia A. Holden
CLIENTS: CA DTSC, UC CEIN (Hilary Godwin/Timothy Malloy/UCLA)
FACULTY SPONSOR: Patricia A. Holden

STATEMENT
Nanotechnology is the understanding and control of engineered materials at dimensions of 1 to 100 nanometers, i.e. at the “nanoscale” (NNI: http://www.nano.gov/html/about/home_about.html). Engineered nanomaterials (ENMs) are designed to exhibit novel or enhanced properties that affect their physical, chemical, and optical behaviors, in effect presenting new opportunities for biotechnology, energy, transportation, agriculture and consumer products. Already, ENMs are used in cosmetics, clothing, sports equipment, coatings, and electronics (http://www.nanotechproject.org/). It is estimated that global sales of ENMs could exceed $2 trillion by 2015 (Hullmann 2007). Simultaneously, questions have arisen regarding the potential environmental and health effects of ENMs whose properties are, by design, different from their constituent elements (Wiesner, Lowry et al. 2006). Early efforts to inform and adopt appropriate environmental health, safety (EHS) and product stewardship practices have the capacity to preempt negative environmental consequences (Murashov and Howard 2009). Competing processes will shape the outcome: the rapid development of new ENMs, yet relatively slow knowledge generation regarding ENM toxicity and environmental fates, the publication of generalized ENM safe-handling guidance documents internationally, and yet the lack of consensus regarding how to regulate ENM use.

Currently, there are no specific, either federal or state, governmental regulations of ENM EHS and waste management practices. In 2009, the California Department of Toxic Substances Control (DTSC) began soliciting industry for information that could influence regulation for one type of ENM, carbon nanotubes (http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/index.cfm). In the coming years, DTSC plans to expand their information “call-in” to include more ENM types. How will the information be used? As DTSC considers developing regulations, what should be the content and orientation of regulations, should they arise? Governments worldwide are debating such concerns.

In the absence of fully understanding EHS and environmental consequences of ENM exposure, regulations regarding safe practices in manufacturing and disposal could be overly conservative (Stern and McNeil 2008), thus thwarting the growth of a potentially promising industry (Choi, Ramachandran et al. 2009). In the interim, many guidance documents for nanomaterials EHS and waste management are available nationally and internationally. Such documents (e.g. from the National Institute for Occupational Safety and Health, or NIOSH) are important for industry and governments at this early stage of the ENM industry, but there are complexities in using them, in that: 1) small research and development labs or manufacturing facilities may be expert in ENM synthesis, but lack either the expertise or resources to extract useable information and implement recommendations, 2) guidance documents have been developed by many different institutions, but a comparative evaluation of practices has not been systematically performed, thus leaving small ENM manufacturers and users to try to select on their own, 3) guidance documents lack an analysis of the economic considerations, thus
perpetuating the barrier to translation and implementation into practice, 4) guidance documents have mainly been developed by EHS experts who may not have the perspective of industry practice during guidance development, leading to guidance that is unrealistic and unlikely to be implemented, 5) most guidance is very general, thus not accounting for specific ENMs and effects associated with their uses. All of these factors have likely led to what was discovered in the 2006-07 survey of ENM industry by MESM students and collaborators: i.e. that most ENM manufacturers have neither developed nor institutionalized practices that address the specific, and potentially very serious, consequences of ENM exposure to humans and release into the environment (Conti, Killpack et al. 2008).

As the CA DTSC begins the process of evaluating the information yielded from their first "call in", they wish to know: 1) what are the recommendations across the currently-available guidance documents, 2) what are reported industry practices, 3) how do the reported practices compare to the guidance documents, taking into account all available guidance documents and a synthesis across them, and 4) how might new policies and regulations assist in the diffusion of management practices and/or impact industry in unanticipated ways? Providing such assessments would enable DTSC to decide what types of policies or regulations may be instituted by them regarding ENM EHS and product stewardship, and what additional information they may need (e.g. by working with NIOSH to test specific practices or guidance recommendations). Thus, this Group Project proposal aims to provide timely synthesis and analysis that can be used by the CA DTSC to address the current complexities in ENM safe handling decision-making, as outlined above. Specifically, this Group Project would: extract from currently-available guidance documents to synthesize a consensus-based set of recommended practices, evaluate the responses from two past Group Projects that surveyed ENM industry practices and also evaluate the DTSC call-in responses, critically evaluate how the recommendations compare to reported practices, assess the economic costs associated with practices that emerge as potentially best by comparing implementation costs within the context of fiscal constraints placed on ENM industries/universities, and consult back to the University of California Center for Environmental Implications of Nanotechnology (UC CEIN) and collaborators including the UCLA School of Law and Stanford University as these parties assist DTSC in potentially developing CA-specific guidance or regulations.

OBJECTIVES

Considering the problem landscape described above, this proposed Group Project aims to conduct research to answer the following questions:

1. **What does industry do?** The Group Project will discover and synthesize across published literature regarding surveys of industry practice, including one performed by Bren MESM students previously (Conti, Killpack et al. 2008), another ongoing (2009-10 MESM Group project), and others performed by government (e.g. NIOSH) and other researchers. This effort would also include assisting UCLA researchers in analyzing DTSC call-in information (due January 31, 2010) and including this dataset in the overall comparisons.

2. **What should industry do?** The Group Project will synthesize across national and international, published, guidance documents, working with UC CEIN experts at UCLA, to define the practices currently recommended for ENM EHS, waste management and product stewardship. This effort will also compare guidance documents to current literature in ENM toxicology and environmental effects, in an effort to critique the efficacy of the former for protecting health and the environment.

3. **What will recommended practices cost industry?** The Group Project will estimate the costs to industry of implementing EHS and product stewardship practices, taking into
account potential staffing, equipment, and other investments for personnel protection, waste management, and workplace and environmental monitoring. The purpose of this effort is to also inform the CA DTSC as they consider potential regulation and the possible burden to individual industries in the future.

4. **How would new ENM industry-specific policies and regulations work within existing or emerging governmental regulatory structures in CA?** The Group Project will begin to evaluate such issues, in collaboration with the DTSC and the UCLA Sustainable Technology Policy Program (Professor Timothy Malloy and law student researcher(s) at the UCLA School of Law. The purpose is to start to define, on behalf of DTSC, how existing State laws may intersect with the development of new policies and potential regulations concerning ENM safe use.

**SIGNIFICANCE**

For perhaps the first time in modern society, governments and citizens are trying to anticipate the environmental and health consequences of a new industrial revolution. This did not happen with the advent of modern agrochemicals and it did not happen in the biotechnology revolution. Yet it can happen with nanotechnology. Not only will this project serve to inform governments, citizens and industries of recommended practices in the industry for protecting health and the environment, but approaching and conducting this work will reveal the possible modes of acting preemptively in the face of new potential environmental and health threats. Students and faculty engaged in this project are expected to learn to what degree anticipatory research activities can preempt environmental and social harm in the face of new industrial movements.

This project would:

- Provide an up-to-date understanding of how industry is currently managing its workplace and environmental concerns in ENMs
- Indicate how close industry practices are to existing recommendations in health, safety and the environment, and how closely recommendations are tracking industry practices
- Provide a critical analysis of guidance documents in light of current toxicological assessments
- Provide an understanding of the investment by industry needed to adopt practices in current guidance documents.
- Help build a framework for policy makers to assess the tradeoffs between economic growth and improved health/safety upon which to base future regulatory decisions.
- Provide a cross disciplinary (science, law, policy) experience for the involved students
- Provide the students with a rich set of outside advisors at UCLA (Godwin, Malloy) and associated collaborators (e.g. DTSC).
- Expose students to a project that is of high concern to CA government and beyond, essentially providing the students with a rare opportunity to influence the direction of currently-unwritten, prospective policies in this new field of nanotechnology. This is a highly publicized issue, and the two national centers (UC CEIN and the CEINT) involved in supporting the research can disseminate widely to national and international sites and organizations. Opportunities for interaction in the interdisciplinary centers will provide professional training for Bren students; mentoring by an advanced UCLA law student will enhance policy-relevant training.
- Provide one full-time equivalent paid summer internship for group members, with a request for a 2nd through the ENVIRON Foundation (see letter of request).
BACKGROUND
The U.S. Environmental Protection Agency’s Nanotechnology White Paper (External Review Draft) (U. S. Environmental Protection Agency 2007) was released to the public in December 2005. This paper indicates that a general disconnect between industry and government exists in the U.S. with regards to ENM safety. Current regulations in occupational safety and environmental protection do not apply to nanotechnologies, but the full extent of regulatory exclusion is not well understood. There is limited information regarding the human health effects of ENMs, and thus even a limited basis upon which to evaluate current occupational and environmental safety standards. NIOSH published a research agenda in 2005 (http://www.cdc.gov/niosh/topics/nanotech/strat_planINTRO.html), and has provided guidance for safe use of nanomaterials (http://www.cdc.gov/niosh/topics/nanotech/). The Bren School has conducted two MESM group projects in ENM EHS, both oriented towards surveying industry. The project in 2006-07 (Conti, Killpack et al. 2008) was the first publically-available international survey of industry, and the results motivated the International Council on Nanotechnology (ICON), the funding agency, to produce the Good NanoGuide, i.e. a “wiki” that would inform industry which was the main constraint indentified in the 2006-07 survey (http://www.goodnanoguide.org/Basic). In 2008, two NSF- and EPA-funded national centers in the environmental implications of nanotechnology were initiated. The UC CEIN, joint between UCLA, UCSB, other UCs, and other institutions worldwide, has co-sponsored, with the NSF-funded Center for Nanotechnology and Society (CNS at UCSB), a 2009-10 MESM group project that is a new survey of industry practices with an emphasis on risk perception.

This proposal follows, and builds upon, the two prior MESM projects, while aiming to support the DTSC, UC CEIN, and other stakeholders in a new phase: i.e. one of better defining what should be recommended for safe use and disposal of ENMs and thus one of helping potential regulators to proceed in the best interest of all involved parties.

STAKEHOLDERS
CA DTSC, NSF- and EPA- funded UC CEIN; UCSB EHS (Dave Vandenberg, as an interested party); the UCSB CNS; the UCLA Sustainable Technology Policy Program; U.S. Environmental Protection Agency; The National Institute for Occupational Safety and Health; National Nanotechnology Initiative; National Science Foundation; Worldwide OSH agencies; Nanotechnology companies; Workers in the nanotechnology industry; Communities in which such industries are located; End-users of nanotechnology products (consumers, general public, environment)

APPROACH AND AVAILABLE DATA
Approach: We propose a project that, while having a distinctive Group Project product, is a highly collaborative opportunity for the students involved. Working on direct behalf of the UC CEIN (Professors Godwin and Malloy of UCLA), the Group Project will conduct its research in three phases. The first phase of the project (Spring 10) will be a multi-country and cross-agency delineation, analysis, and summary of currently-available ENM EHS and waste management guidance documents. Upon completion of the initial stage, data will be summarized and reviewed, and an initial report of the findings generated. The second, simultaneous, stage of this project will involve evaluating the results of surveys of industry practices, using published literature as well as insights gained from the 2009-10 group project and possibly the DTSC call-in. This phase will culminate in a written comparative analysis of reported and observed industry practices in comparison to synthesized guidance documents. The third phase, likely in
Fall 2010, will involve developing a cost analysis and evaluation of the regulatory and policy approaches to encouraging diffusion of best practices. This phase, in collaboration with UCLA and the CEIN, may also involve actual testing of equipment and protective gear as recommended by guidance documents, and with the involvement of NIOSH via the DTSC and UC CEIN.

**Data:** Guidance documents are readily and publically available, but the Group Project will be responsible for thorough and complete identification and acquisition of such documents. This will require an immediate effort in Spring quarter, 2010. Surveys that are published are expected as resources for the students as they summarize the actions of industry. While other, unpublished, or “grey literature” surveys may have been performed, some results may not be accessible to nonpaying customers. The DTSC recently visited UCSB and webcasted a seminar throughout the UC CEIN (January 20th, 2010). In a follow-up meeting, the DTSC explained that all of its call-in data will be publically available. Thus, this dataset will also be used and available before this group project commences. Data regarding specifications of EHS and monitoring equipment will be available from manufacturers’ websites, identified from guidance documents and by the Group Project members. Cost information will be gathered from manufacturers and supply companies and should be readily available upon request. Additional information will be sought regarding the financial capacity of a generic (hypothetical) ENM industry firm/university to absorb costs accompanying increased regulation. This financial data will primarily be in the form of investment capital (venture capital, debt, equity, etc.) but will also include existing and projected future revenues for each firm. The data used to assess fiscal constraints must be put in context with the health/environment benefits associated with increased regulation by procuring relevant data on the toxicology relevant to existing nanomaterials’ physiochemical properties. Researchers/academics who are involved with ongoing research on the predictive toxicology of nanomaterials will be consulted to estimate the healthcare/environmental costs associated with each level of possible regulation.

**DELIVERABLES**
The first phase will be concluded with a report of the findings, including a description of research sources. This report will also identify and summarize, plus synthesize across, current guidance documents pertaining to ENM safety which will be a context for any delineation efforts already underway. Phase two will produce a document that is a comparative analysis of industry survey results and guidance document recommendations. Phase three will produce a report assessing the economic tradeoff between industry growth and improved health/safety based on an analysis of available financial data, industry projections, conservative/optimistic estimations of nanomaterial toxicology and relevant healthcare/pollution remediation costs. It will also include legal and policy analysis of methods for encouraging diffusion of best practices. Materials will be disseminated via the website clearinghouses of the UC CEIN and through a website for this Group Project.

**RESOURCES**
Resources are available through the UC CEIN (UCLA, Godwin) for the equivalent of 1 full time summer intern. Resources will be requested for the equivalent of another full time internship over the summer through the ENVIRON Foundation (see letter of request). Professor Malloy of the UCLA Law School will serve as an outside advisor for the legal and regulatory evaluations. An Industrial Hygiene graduate student at the UCLA School of Public Health, advised by Professor Godwin (UCLA), will co-advice students in the assessment of guidance documents and in the comparisons to recently-published toxicological studies. Professor Magali Delmas at the UCLA Institute of the Environment will be requested to serve as an expert regarding industry perspectives.
REFERENCES


