2009 Environmental Health Summit: Environmentally Responsible Development of Nanotechnology

Recommendations from the Research Triangle Environmental Health Collaborative

Representing a Collection of Opinions

Nanotechnology holds great promise for revolutionizing many fields, including material engineering, electronics, energy, and medicine. It is widely accepted that as engineered nanomaterials (ENMs) are increasingly produced and incorporated into a variety of products, their eventual release to the environment across many stages of their lifecycles and via multiple routes of exposure is inevitable[1-3]. The very properties that render ENMs uniquely useful in their applications also may change how they interact with and effect the environment upon their release; for instance, their small particle size enables nanoscale particles to cross or circumvent biological barriers or synthetic filters that are impenetrable to larger particles. This knowledge, in combination with the uncertainty of the impact these novel materials may have on human and ecological health, has generated a growing interest in research on their potential effects.

The development of basic and applied scientific understanding of these effects will help inform safe production, handling, use, and disposal procedures in a way that preemptively avoids negative impacts. However, as with other technological revolutions, the science of nanomaterials and their effects is emerging in parallel with development, commercialization and regulation. With the nanotechnology industry in its nascent stage, there is still time to incorporate information about its human and environmental effects into the thoughtful development of nanomaterials and the products they enable. Sharing information across sectors should foster more benign and economically stable instantiations of this powerful new set of technologies.

In particular, the potential impact of nanomaterials on the environment may influence their commercialization. Although astronomical predictions of economic impact from nanotechnology may not meet the pace predicted at the turn of the century, a wide range of markets and applications are sure to be affected by this general-purpose enabling technology [4]. In 2009, Lux Research estimated that raw nanomaterials represented around $1 billion in revenue, intermediates $29 billion, and final products as much as $224 billion in economic sectors ranging from personal care to automobiles to construction. A recent review of barriers to entry or growth in the nanotechnology sector in North Carolina identified lack of venture capital as a key inhibitor of new business, resulting in part from uncertainty regarding potential negative impacts on human health and the environment and the unknown financial liabilities [5]. However, in today's economic environment in particular, the chance to foster a new market represents a remarkable and important opportunity. Bozeman *et al.* presented the stakes as such:

> "The extent to which commercial potential in [nanotechnology] is achieved…, and the speed with which the United States achieves it, will depend in large part

on the extent to which barriers to companies' adoption and integration of nanotechnology can be identified and then lessened." [5]

Given the confluence of a well-established biotech industry, a developing nanotech sector and world-class educational institutions that characterize the Research Triangle and Piedmont Triad regions of North Carolina, fostering a strong nanotech industry is particularly appealing. Market research shows that over the near term academic research, drug discovery, and drug delivery are the most likely sectors to be initially affected by nanoengineering. It is further predicted that most drug discovery, biosensing, and research applications will be based on the addition of nano-enabled components to existing biotechnologies, thus rendering the intersection of these specific areas of expertise uniquely valuable [6].

It is with these considerations in mind that The Research Triangle Environmental Health Collaborative (RTEHC) sought to explore the myriad of issues surrounding the nano-manufacturing landscape by convening a summit entitled "Environmentally Responsible Development of Nanotechnology" on October 8-9, 2009 at the North Carolina Biotechnology Center. Participants and experts were drawn from a variety of nanotechnology stakeholder groups, representing small, medium and large sized nanotechnology companies, academia, government, the legal community, media, market research and professional services firms, and public interest groups. The charge for summit attendees was to explore critical issues regarding potential risk across nano-enabled product lifecycles, with the goal of generating a set of recommendations for North Carolina businesses regarding how to address such risks. Near-term recommendations resulting from this meeting are summarized here, along with many questions that should be considered in the interim to arrive at more solid long-term recommendations.

The inclusion of this wide assortment of perspectives enabled the summit to consider a multi-dimensional approach to eliminating barriers for small, medium and large sized nanotechnology companies, so they might grow and process/utilize nanotechnology in the most environmentally responsible ways possible according to the state of the field at any given time. The first Environmental Health Summit, sponsored by the RTEHC in 2008, demonstrated that such interactions among diverse fields reveal a broad understanding of the challenges presented[7]. At the same time, the specifically defined focus – facilitating environmentally responsible development of the nanotechnology industry in North Carolina – directed the efforts toward identifying actionable, near-term recommendations. These issues and research strategies have been discussed at many workshops and the current challenges and data needs have been proposed [8-10].

Conclusions

Although the points of view varied and multiple perspectives were captured in the recommendations forged during the summit, the collective concerns of the group centered around the simultaneous yet interdependent development of the industry, the need for data about the potential environmental and human health risks of ENMs, and the application of existing and future regulation to protect human health and the environment.

Three working groups worked in parallel, each focusing on a particular phase of the nanomaterial lifecycle in order to identify business needs and knowledge gaps as to each lifecycle phase. Each of the three groups, 1) Nanomaterials Fabrication, 2) Nanomaterials Integration into Products, and 3) Nanomaterials Disposal and End of Life (EOL) Issues, generated some detailed recommendations tailored to that particular life cycle phase. For the purposes of this document, it is assumed that readers have a familiarity with life cycle phases and the types of risk issues inherent to each phase, *e.g.*, worker exposure during manufacturing, consumer exposure during use, eventual release to the environment during end of life, etc. Across the life cycle, consensus emerged that some meta-level needs must be addressed to enable the more detailed recommendations to be carried out. These overarching recommendations, called preliminary recommendations herein, may assist nanotech businesses in developing and commercializing products of nanotechnology in environmentally responsible ways. In addition, regulatory bodies, research communities, and supporting services may also find the recommendations to be helpful. The recommendations focus around organizing a nanotech community to facilitate the iterative identification, development, and dissemination of nanotech safety and risk information among interested parties.

To date, most nanomaterial safety and environmental risk meetings result in a wish list of data that must be completed and questions that must be answered before conclusions can be drawn. This identification of informational needs is an important and necessary part of a methodical process of addressing an emerging potential risk. The summit, by contrast, generated specific calls for action from targeted groups, focusing on informing current strategies for mitigating risks that can only be fully understood in the future.

The preliminary recommendations outline actions that may be taken by a mix of nanotech stakeholders or leaders, such as the participants of the summit, to support industries in developing guidelines for the responsible commercialization of nanotechnologies. They require the input of the business community and the assistance of a greater network of supporting stakeholders, including regulatory bodies, research communities, legal, insurance, and other risk management service providers, venture capitalists and financial services firms, public interest groups, and non-profit organizations. This document, however, is not intended to be a legal or other official advisory resource, and should not be construed as such. Rather, its purpose is to collect ideas, help link members of the nanotech community within the state and beyond, and facilitate the sharing of expertise to forge a path toward the environmentally and fiscally responsible support of this developing set of technologies. The clientele for these guidelines would then be primarily existing or prospective nanotech businesses in North Carolina that must manage a variety of nanomaterial risks. Stakeholders in all regions, however, would benefit from this document.

Preliminary Recommendations

These recommendations are directed to a variety of stakeholders and pertain to multiple stages of the nanomaterial life cycle. The figure below presents a schematic of the roles and responsibilities for some key stakeholder groups associated with responsible management of nanomaterial risk. The functions of the proposed organizations would be to formalize and

facilitate the communication between these groups in support of their roles and the collective goal of furthering nanotech industry development while protecting the environment and human health from any potentially negative effects.

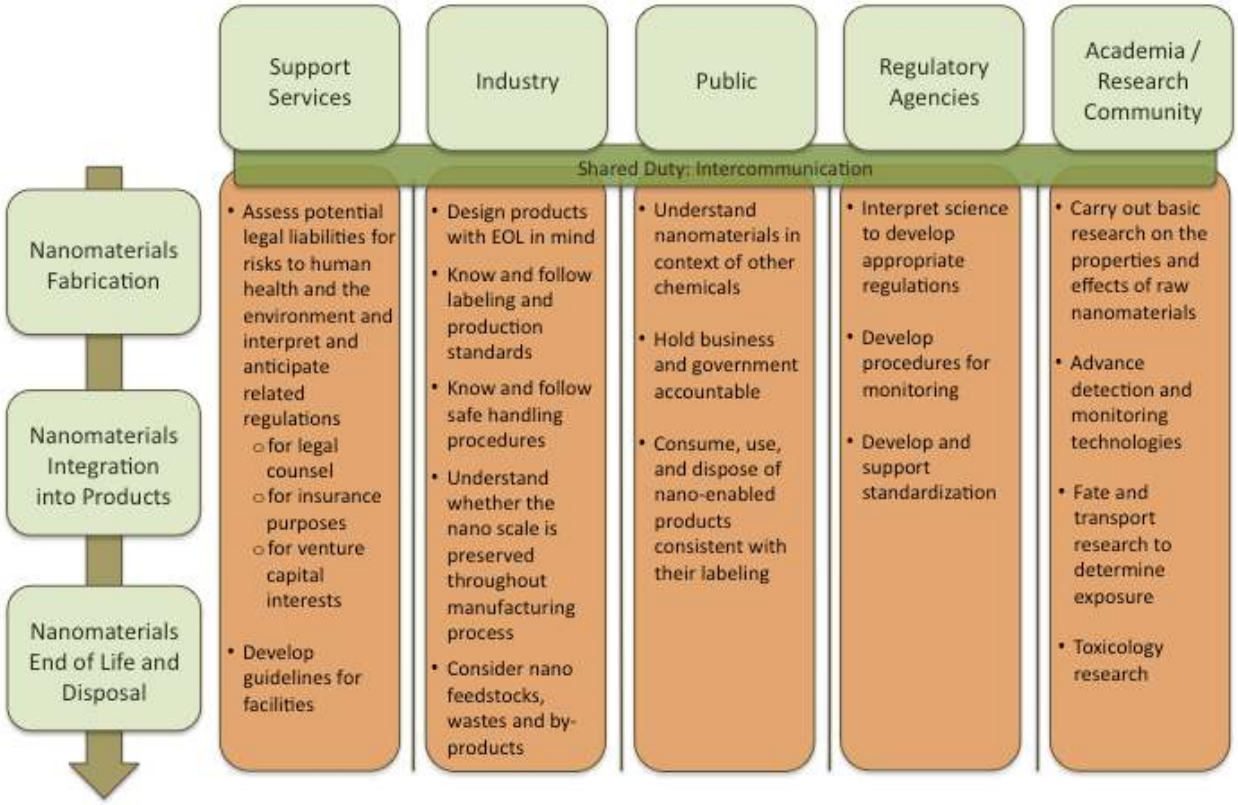

Figure 1: Schematic of nano-safety roles and responsibilities

These recommendations, precursors of detailed business recommendations, are centered on three categories of efforts to assess and manage the risks of nanotechnology to human health and the environment.

I. Create a nano information infrastructure iteratively to identify, organize, and disseminate information to relevant parties including industry, government, educational institutions, and the public. Several suggestions were made with respect to this main issue.

1. Establish a trade association focused on both advocacy for and assistance to North Carolina nanotech businesses. A state level trade association may be the most effective first step. Such an organization would also include input from legal and financial service providers, insurance companies, and non-governmental organizations; appropriate membership is currently being assessed. Several high priority summit recommendations fell under this category:

1.1. Identify existing occupational and environmental risk guidance information and assist small, medium and large businesses in developing EH&S guidelines to minimize potential risk and any corresponding regulatory and legal exposures, which should include a review of applicable governmental regulations or guidelines and applicable

industry voluntary standards or best practices. Iteratively gather and disseminate information regarding:

- Best technologies and practices for instrumentation and fabrication monitoring, safe handling procedures, and personal exposure monitoring, drawing on NIST (National Institute for Standards and Technology), NIOSH (National Institute for Occupational Safety and Health) and Good Nano Guide (International Council on Nanotechnology, Rice University).
- Reporting and records retention requirements for production levels, based on new and existing regulation of ENMs, *e.g.,* FIFRA (Federal Insecticide, Fungicide and Rodenticide Act), RCRA (Resource Conservation and Recovery Act), HMTA (Hazardous Material Transportation Act), the European Union's chemical management program, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), TSCA (Toxic Substances Control Act), EPCRA (Emergency Planning and Community Right-to-Know Act), and state analogue authorities, etc.
- Standardization of any applicable hazardous material labeling, packaging, and shipping procedures in concert with DOT (U.S. Department of Transportation).
- Immediate risk management activity for minimizing regulatory enforcement and potential civil legal liability risks and potential legacy issues.
- Insurance availability under current commercial general liability and product liability insurance policies, worker's compensation insurance policies, and the emerging availability of specialty nanomaterial or nano-product insurance products by specific insurance carriers[11].
- Consensus definitions for nanomaterial descriptive terms and hazard categories using compositional and physical attributes, drawing on ANSI (American National Standards Institute) and ISO (International Organization for Standardization) recommendations.
- Limiting or potentially eliminating exposure of workers, consumers, and environmental receptors.
- Instrumentation and methods sensitive enough to quantify nanomaterials in occupational and environmental settings to support and validate regulatory compliance.

1.2. Represent the interest of nanotech companies and advocate for financial support and business incentives at the state government level.

1.3. Work with the State Department of Commerce to assist small and medium-sized enterprises (SMEs) in overcoming prohibitive costs of doing business by coordinating mutually beneficial collaborations; for example, *via* the creation of a SME nanomaterial disposal collaborative.

1.4. Interact with and advise DHHS (U.S. Department of Health and Human Services), EPA (U.S. Environmental Protection Agency), OSHA (Occupational Safety and Health Administration) on North Carolina nano-facilities.

1.5. Establish links to NNI (National Nanotechnology Initiative), SOT (Nano) (Society of Toxicology (Nano)), SRA (Society for Risk Analysis), AACT (Nano) (American Academy of Clinical Toxicology), ACT (American College of Toxicology), AAPS (American Association of Pharmaceutical Scientists), ACS (American Chemical Society), NIA (Nanotechnology Industries Association), and the ACC Nanotechnology Panel (American Chemistry Council).

1.6. Assist in the development of best practices for companies (large and small) to manage environmental and human health risk.

1.7. Hold annual professional meetings and workshops in North Carolina.

2. Support the establishment of an authoritative standardization organization dealing with nanomaterials as well as related instrumentation; ideally part of a U.S. national reference lab like the National Institute of Standards and Technology (NIST) or the ANSI-ISO TC-229 Nanotechnologies organization would carry out the following iterative, updatable responsibilities:

2.1. Develop separate standards and reference materials for key nanomaterial characteristics, such as precise size, shape, and manufacturing method. Establish and communicate protocols for adequate characterization materials and methodologies by material category (i.e. Certificate of Analysis).

2.2. Provide recommendations on disclosure rules with regard to MSDS (Material Safety Data Sheet) documentation, determining any addendums or clarifications needed to cover characteristics unique to the nanoscale.

2.3. Build on existing ASTM (American Society for Testing of Materials) and ANSI-ISO guidance, and confer with other established organizations in developing and refining standards, including:

- The American Chemistry Council (ACC) regarding material production and characterization standards
- The American Institute of Architects (AIA) regarding guidelines for nanofabrication facilities, as they exist for hospitals and other specialized
- The Nano Science and Technology Institute (NSTI) regarding best practices
- The NanoBusiness Alliance (NbA) regarding best practices

2.4. Develop qualifications and certification of materials, *e.g.*, HEPA (High-Efficiency Particulate Absorbing) for safety related equipment, both for personal safety equipment and for ambient air quality within facilities. Interim measures should be defined until such time as effective methods exist for managing <100nm particles.

2.5. Define an accepted method for carrying out risk analysis specifically enough to increase ability and credibility but based on tailored testing to keep the process manageable, and

build a framework using examples such as the DuPont/EDF Nano Risk Framework and the Good Nano Guide. Create an interoperable database of risk assessment on materials being developed globally, which could be arbitrated for example by the Organization for Economic Cooperation and Development (OECD).

3. Coordinate a statewide nano-education mission that permeates all levels of education, with the goal of developing a nanotech aware public and a prepared nanotech workforce to support a growing and safe nanotech industry, while also developing and incorporating "ELSI" (Environmental, Legal, and Societal Implications) awareness and principles.

   3.1. Determine what to teach:
   - Technology
   - Safety
   - Toxicology
   - Environmental exposure and effects

   3.2. Support programs across K-12, community colleges, masters and doctoral programs, and offer outreach to public presenting what nanotechnology is along with its benefits and risks.

   3.3. Systematically develop nano-industry worker training to support a workforce of technicians skilled in nanoparticle synthesis, characterization, measurement, and detection processes, as well as health and safety practices.

   - Use Golden Leaf Biomanufacturing Training and Education Center (BTEC) as the model. BTEC serves as catalysts in establishing, attracting and expanding biomanufacturing in North Carolina by providing "a wide variety of high-quality educational and training opportunities to develop skilled professionals for the biomanufacturing industry, thus contributing to the social and economic well being of the industry and state."

   - Coordinate with community colleges to develop curricula supported by Universities with nano expertise and connected with local nano businesses.

   - Seek state level investment in grants to university extension services to develop these programs and their related outreach needs.

II. Creation of a Decision Tree for near-term business decisions

A recommended kick-off activity of the aforementioned local multi-stakeholder organization is the development of an evolving decision tree that companies could follow to determine quickly and easily how best to adhere to current nano-manufacturing best practices. With data expanding regularly, any decision guide of this sort will need to be dynamic and updated regularly. Invited

participants could represent organizations such as the North Carolina Department of Environment and Natural Resources, the Department of Agriculture, the previously recommended nanotech trade association, the Commerce Department, and the Environmental Health Collaborative. ELSI considerations would have to be addressed and incorporated in a manner to maximize public transparency.

1. The decision tree must be easy to follow, precise, and designed in conjunction with the existing regulatory framework. State of the art data sets must be included.

2. The initial structure could be determined based on a variety of entry points, or starting categories of the decision tree.
    - Based on grouping businesses according to supply chain location: raw nanomaterial nano-manufacturer, intermediate user, incorporator into final product, disposal service company
    - Based on likely routes of emission to the environment: wastewater, air, solid waste
    - Based on category of nanomaterial type: which elements are involved, dry powder, solid polymer matrix, non-solid polymer matrix, liquid dispersion

3. The decision tree structure must enumerate all the ways through which nanomaterials may be released into the environment and/or may result in human exposure, and for each potential route of release or exposure, provide the proper care and disposal requirements

    - Direct vs. indirect
    - Intentional vs. unintentional
    - From various life cycle stages
    - Manufacturer disposal
    - Consumer use
    - Recycling
    - Consumer disposal
    - Via various exposure vectors
    - Municipal solid waste
    - Biosolids
    - Wastewater

III. Creation of incentives for new/retooled industry development and current industry investment in best practice nanomaterial procedures.

In addition to compiling the most up-to-date and accurate information to inform the best handling of nanomaterials throughout their lifecycle, consideration must be given as to how to incentivize companies to subscribe to such a decision tree, and to ensure there are no hidden penalties for participation. Most of these incentive initiatives would require a state commitment to funding.

1. Develop a certification program or seal of approval as analogous to the "energy star" program to reward those companies that provide the most transparency of nano data or

implement the most rigorous safety and handling procedures, which would serve as an agreed upon standard that public can understand. Members of such a "nano star" program would contribute to a fund dedicated to addressing EOL issues. It is important to recognize that the larger companies would be able to participate while SMEs would encounter more financial limitations. If the nano-community supports the sentiment that a rising tide raises all boats, such a fund could be seen as a win-win by enabling small companies to develop in environmentally responsible ways while rewarding the larger companies with favorable branding.

2. Provide financial incentives for preemptive engineering of products for self-destruction or environmentally responsible recycling or disposal. Prioritize ENMs with suspected high toxicity.

3. Fund the development of nano-EHS infrastructure to support and formalize existing business operations and to provide incentive to new industry in the state, focusing on developing specific areas such as the nano disposal industry.

Urge government agencies, including the EPA, the U.S. Food and Drug Administration, and other NNI member agencies, and pertinent state government agencies, to continue to develop the data, tools, programs, and infrastructure needed to sustain and nurture the responsible development of nanotechnology.

1. Federal agencies engaged in the development of environmental, health, and safety data, analytical tools, and related fields of endeavor are essential to the responsible development of nanotechnology. This work is critically important to creating a science-based foundation to the assessment of regulations and related governance mechanisms that may be needed to manage potential risks associated with nanoscale materials.

    - It is essential that these federal agencies continue their efforts, be funded with appropriate resources to develop the infrastructure in a timely way, and work with all stakeholders to ensure governance mechanisms are appropriate and calibrated in a way to foster the responsible development of nanotechnology.

2. Similarly, several states and local governments have assumed leadership positions in fostering the responsible development of nanotechnology. The California Department of Toxic Substances (DTSC) data call-in initiatives and the proposed City of Cambridge, Massachusetts ordinance that was considered requiring the reporting of certain information relating to nanoscale material production activities are illustrative of these state and local initiatives. The Commonwealth of Massachusetts has formed an Interagency Workgroup on Nanotechnology to coordinate efforts to address responsible nanotechnology development, including sponsoring workshops on best practices for manufacturing and waste management.

    - These initiatives and a growing number of related others are to be acknowledged, reviewed, and considered as possible templates for further action that will assist in the responsible development of nanotechnology in North Carolina.

Near Term Recommendations: Best Management Considerations

Although the information dissemination vessels are in development, it was agreed that some interim recommendations should be generated to capture what was discussed regarding nanomaterial safety and risk questions that existing businesses are currently facing. Throughout the summit, there was considerable discussion about the best way to address the need for best management practices; ideas ranged from the suggestion that the summit attendees develop a list of formal recommendations to the suggestion that any such recommendations should originate from the particular industries to which they would pertain. The existence of such dissenting views in itself points to an area of great importance and highlights the need for a body of stakeholders that would wrestle with these issues and come to an agreement on how best to handle this undeniable fact: in the present, recommendations are needed based on the information available to facilitate the safest possible business growth, advising companies in a pragmatically useful manner as to what they can do today to manage nanomaterials throughout their lifecycles in good conscience.

To this end, four current Best Management Practices were compiled.

1. First and foremost, limit exposure to ENMs.
    - Proactively engineer products; *e.g.*, engineer nanomaterials for responsible disposal by using green materials, designing in self-destruct characteristics based on persistence properties, and designing to facilitate recycling.
    - Proactively engineer processes; *e.g.*, in the absence of research on whether nanomaterials released to municipal wastewater and solid waste pose a hazard, characterize and separate waste streams.
    - Draw on work regarding green nanotechnology, looking at limiting exposure to all inputs and byproducts throughout the lifecycle and focusing on preventative approaches to moving forward[12, 13].

2. When handling a nanomaterial in the workplace, all reasonable precautions should be undertaken to avoid or minimize unnecessary human and environmental exposure to the nanomaterial. Bright-line statutes and regulations relating to the use of nanomaterials are slowly emerging, and toxicological information is also expanding. Responsible stewardship is an absolute necessity when dealing with nanotechnology, and that means utilizing available resources and experts to gather information, analogizing to similar situations involving non-nano materials, and making intelligent decisions about the use of these materials. With respect to disposal of nanomaterials, existing laws and regulations define what is or is not hazardous and such laws and regulations apply to nanomaterials.

3. Make an environmental health and safety-specific effort to stay informed on emerging nanomaterial developments by checking resources such as the Good Nano Guide

(www.goodnanoguide.org), or the National Nanomanufacturing Network InterNano Project (www.internano.org)

4. Actively participate in the previously recommended nanotech trade association as it develops.

About the Research Triangle Environmental Health Collaborative

The Research Triangle area of North Carolina is unique with respect to the number of world-class organizations focused on the environmental health research and policy. Given the outstanding depth and breadth of environmental health expertise in academia, government institutions, non-profit foundations, and private businesses in the area, the Research Triangle has become the epicenter of contemporary thinking about environmental health.

To take advantage of these intellectual resources, the Research Triangle Environmental Health Collaborative (the Collaborative) was established as a non-profit 501c3 organization. The Collaborative supports a united environmental health resource that connects organizations and institutions; links research and policy; and joins government, academia, industry and public interest groups to mutually consider, discuss and debate the future of environmental health on a state, regional, national and international level. It provides a neutral forum to host candid discussions and to provide advice on the most significant issues facing environmental health and related public policy. The goal is the creation of partnerships to enhance global environmental health. www.EnvironmentalHealthCollaborative.org

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