

United States House of Representatives
Committee on Science

Hearing on:

“Research on Environmental and Safety Impacts of Nanotechnology:
Current Status of Planning and Implementation under the National
Nanotechnology Initiative”

Testimony of:

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Summary

I am executive director of the multi-stakeholder International Council on Nanotechnology (ICON), and director of a federal research center in nanotechnology, and these roles have informed my opinions of the federal government's approach to nanotechnology risk research. I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify and prioritize the research needs in this area. The urgency to nano-EHS research affects the entire NNI investment. This group should provide a full strategic plan within a year, and engage a broader community in authoring this document. The apparent agency boundaries that are currently used to classify the research needs should be removed, and instead these needs should be grouped and linked to larger unifying objectives – such as the development of predictive models for nanomaterial's impacts on the environment. These organizing goals should be described so that it is clear how they help transition us from a climate of uncertainty with regards to nanotechnology's risks to one of confidence. Finally, the NEHI prioritization misses the critical needs related to uniform methods, data structures and languages for nanotechnology risk researchers. There should be a clear plan to support the research harmonization activities so that the policymakers can extract – within a few years – consensus answers to key questions in this research area. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology wide open for innovations.

Thank you Mr. Chairman and members of the Committee for the opportunity to speak about the environmental, health and safety (EHS) research needs for nanotechnology. Today, I am providing my individual opinions, but they have been informed by my association with the International Council on Nanotechnology (ICON). ICON was established in 2004 by a coalition of academics, non-governmental organizations, industry and governments. This organization, based at Rice University, is a public-private partnership founded on the principle that multi-stakeholder, international collaboration is an essential ingredient for effective risk management of nanotechnology. As its executive director, it is my great honor to work with its director, Kristen Kulinowski, and our many volunteers from around the world on projects ranging from a free, searchable database of EHS research papers to a survey of current practices for nanoparticle handling in the workplace.

ICON's most recent effort is an international research needs assessment project – funded in part by the National Science Foundation (NSF). We have used the global reach of our volunteers to recruit diverse stakeholders to international workshops, where we asked them to assess the research needs for nanotechnology EHS. The first step in this process is to evaluate known information about these connections and identify where resources should be directed to address knowledge gaps. The ultimate goal envisioned by this project is the design of biocompatible and environmentally benign nanomaterials through the development of a framework that enables prediction of interactions based on physicochemical properties of engineered nanoparticles. The framework contains priorities to enable improved risk assessment over time as new nanomaterials or applications are developed. Armed with this knowledge, we can work together to develop safe applications of nanoscale materials or, in cases where the risks are too great, an alternative to their use.

Given this background, and my own experiences as a practicing nanotechnologist and director of the NSF Center for Biological and Environmental Nanotechnology, I will comment on the latest National Nanotechnology Initiative (NNI) document concerning nano-EHS research needs.

I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify the research needs in this area; however, there is an urgency to nano-EHS research that affects the entire NNI investment. Innovation in nanotechnology is being threatened by the uncertainty about its risks and how government will manage them. We need this innovation more than ever right now. Nanotechnologies offer new approaches to treating cancer and cleaning water, and may enable energy independence for our country; but fewer of these transformative technologies will make it into commerce if the technology transfer pipeline becomes clogged by concerns about nanoparticle safety. This problem cannot be solved by increasing the inputs to the pipeline, nor should it be addressed by relaxing regulatory oversight. The only sure fix is high quality and intelligently packaged risk-related information.

Going from a climate of uncertainty to one of confidence in managing nanotechnology risk is a massive undertaking that will take years to fully develop. It will also take careful planning and coordination among agencies in this government and abroad. The 2007 NEHI report is an important first step towards creating a coherent and effective strategy for nanotechnology's EHS research, but by summer of 2008 there should be a full and detailed strategic plan made available. As it makes clear in its title, this report is not a strategy. The steps proposed to getting to a strategy are reasonable and deliberative; however, I would recommend sacrificing some of them (the gap analysis for example) because of the urgency of this issue.

Break down barriers between agencies

The NEHI working group could greatly improve future documents by working to break down the apparent agency boundaries that define its approach to this area. The needs in this area are all cross-agency, and an effective strategic plan cannot look like it was created by agency silos. It appears that the various sections of the report were authored in large part by agencies working separately from one another. Section 2, for example, is clearly related to the NIST mission; section 3 to the NIH mission and section 4 to the EPA mission; sections 5 and 6 to NIOSH. Also, it is not clear that each agency should get five priorities; some agency activities need to be greater in scope in the beginning and taper towards the end of the program for example.

A missing agency in this discussion is the Department of Energy (DOE). DOE has a large investment in nanotechnology through its network of nanotechnology facilities, and is thus an immediate customer for information about risk management in a research setting. Moreover, the DOE has enormous capability for particulate and molecular contaminant transport in air, water and soil, with unparalleled experimental and computational capacity. In addition, DOE manages existing programs that seek to understand how nature both produces and uses natural nanoparticles and this perspective is of great value in risk research. For all of these reasons DOE should be a more active participant in the planning process. Like any agency, it should not receive any unfunded mandates. However, I believe that in the area of environmental exposure (fate, transport and modeling) of nanoparticles it is a key partner.

Also apparently missing is the role of the National Science Foundation in nanotechnology risk research. Currently, NSF is the single largest funder of nano-EHS research among the agencies; while risk research is not as clearly connected to NSF's mission, I would argue that this investment is an excellent one for both nanotechnology and fundamental science. In particular, the challenge of predicting the interactions of nanomaterials with the environment is one that will bring together new disciplines in computational biology and bioinformatics – disciplines nurtured in large part by the NSF.

A strategic plan needs several unifying objectives

The prioritization document provides 20,000 foot agency-specific views of this problem, but it never brings these together into a 50,000 foot view of exactly how each research need will transition us from a climate of uncertainty to one of confidence. I believe this disconnect may exist because of the silo approach to writing this report; this division is not a general feature of the NNI and risk research, and I note with great appreciation the productive coordination among EPA, NSF, NIOSH and NIH already with respect to current funding in the area. These agencies know how to work together; they just didn't convey that fact very effectively in this current report. As a result of this, the overall document left me without a sense of the shared objectives that will drive the program. The ultimate strategic plan must be structured by two, maybe three, overarching outcomes that stakeholders agree will give us more confidence in managing risks.

During our ICON workshops, we structured debate around the shared objective of predictive models for nanotechnology risk. There was great enthusiasm for framing the problem this way among scientists with research and regulatory missions alike. Nanotechnology throws a curve ball at conventional risk assessment, which is designed to evaluate the risk of a single substance like DDT. Its basic materials can be created with millions of possible variations of different sizes, shapes, surfaces and chemical type. Faced with such variety, we can't just apply a risk tool over and over again. Instead, we have to predict based on measurable properties how nanomaterials might move into organisms, and to then use informatics models to link their presence to an impact such as toxicity. Such a concrete outcome is the best starting point for the NNI's planning process.

Engage external stakeholders in developing Grand Challenges for Nano-EHS Research

The NEHI's work would benefit greatly from a more open process that engaged external advisors not only as commenters on the document, but also as authors. This report was made available for public comment for one month, and comments were restricted to the 'principles used for prioritization,' not the actual priorities. The NEHI would benefit greatly from convening external advisors for the next stage of the process; in the least, this engagement could accelerate the drafting of the full plan. I would point to the NNI grand challenge workshops (2000 – 2003) as a model for this activity. These events drew researchers from all sectors together to draft the language of 'grand challenges' in area of nanotechnology related to information sciences, biology, materials and manufacturing as well as environment. Reports from these meetings often included prioritization of issues and in some cases rather detailed plans about how best to proceed with research in the area. I think especially for this topic that engagement of multiple stakeholder groups is essential. The NNI should hold 'Grand Challenge for Nanotechnology Risk Research' workshops and structure them in such a way as to directly input into their planning – and convey that structure to the participants. Engaging external advisors as real partners in the planning process should accelerate the pace of this activity and ensure the planning document is well integrated with other global efforts.

Support harmonization of language, methods and materials

Finally, there should be a clear plan to support activities devoted generally to harmonizing researchers' languages, methods and materials. These issues were mentioned in 2006, but this year only a need for reference materials made the cut. At the ICON workshops, it was hard to get participants to stop complaining about how the lack of standard terminology, data structures, methods and reference materials made their research slower and less conclusive. Overwhelmingly, participants agreed that harmonizing research methods was a critical first step in a global nano-EHS research effort.

To understand why this issue is so important consider the difference between funding applications research versus risk research. In the first case you might fund five teams to build a better battery, each with its own approach, but in the end you get what you want if only one team manages to improve the battery. In the second case, if you fund five teams to help understand nanotube toxicity and they get five different answers you are actually worse off because your research creates uncertainty rather than combating it. Unfortunately, such dissonance in the technical literature is normal for new types of science and what we are trying to measure (nanotechnology's risks) is very challenging. We researchers cannot really tackle the problem until we have a mechanism to deliberate, argue and ultimately agree on what to call nanomaterials and what protocols to follow in doing the risk research.

The harmonization that I envision will not mean that there will be consensus among the technical community on elements of nanotechnology's hazard and exposure; rather, that we will reach consensus faster because we will not be arguing through the slow channels of peer-review about methods and language. The most important features of this harmonization activity are that it must result in voluntary practices, designed by the active researchers in nano-EHS through a collaborative and consensus process. Top-down and mandatory instructions about how best to collect data, organize it or report would be a disaster. A great model, mentioned in the NNI's 2006 report on nano-EHS needs, are the MIAME standards for protein arrays; these are driven by researchers and NIH had the good sense to fund workshops and a website to keep them updated. To get this started for nanotechnology would require a good nano-EHS network of researchers; NSF has examples of network funding for community building in other areas. This community would convene a few workshops, use the electronic data-sharing possible via the web, and perhaps contract the services of a technical writer. Round robin tests of methods and materials would follow from any uniform practices that emerge in a Phase 2 of the harmonization program.

It is important to realize that the standardization efforts underway at ASTM and ISO are not equivalent to what I am referring to a research harmonization. I chair the ASTM E56 committee on nanotechnology and over the past few years have developed a good familiarity with international standardization. I have enormous respect for these processes, but they are poorly suited for the task I envision. First, academics are not traditionally represented in these activities. Indeed, I am one of

the few academics actively involved in nanotechnology standardization and I cannot see that changing. Second, research harmonization could in principle happen over the span of nine months and several workshops; even a straightforward ASTM standard could take two years. Third, there are real issues with international participation in either ASTM or other standard developing organizations, including the International Organization for Standardization (ISO). US scientists can only write standards by being on ASTM (unless they are nominated to the US technical advisory group to ISO), and foreign scientists are usually expected to participate in their national standards activities – to which ASTM is a competitor. Fourth, international standardization is highly politicized and any document takes on legal and commercial scrutiny that is out of place when researchers are discussing the nitty gritty details of evaluating cell death, for example. Finally – and most problematic – standards documents from ASTM and ISO are copyrighted and expensive. The research harmonization documents need to be freely available to anyone with a computer – they have to be easy to use and access.

It may be that the research harmonization documents could serve as starting points for more formal standardization in ASTM, ISO or elsewhere. In this model, research harmonization activities would be a precursor not a competitor for formal standardization processes; in this way, they could better serve the immediate needs of the research community.

Conclusion

In conclusion, I hope that the NNI can quickly, with external input, develop a detailed strategic plan. Breaking down risk research into several concrete outcomes – such as predictive simulations – will help to rally the scientific community and create public confidence in existing and new nanoproducts. Perhaps the first step will be programs that catalyze the research community to develop and adopt common practices for nanotechnology risk research. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology innovation flowing.

International NanoEHS Research Needs Assessment:

A Preview of Reports from Two Workshops

ICON sponsored two workshops this year to discuss the research needed to enable prediction of nanomaterial impacts. The first workshop, held at the National Institutes of Health campus in Bethesda, MD in January, tested whether nanomaterial composition was a reasonable way to begin classifying nanomaterials for predictive purposes and where in the lifecycle of a given class of nanoparticle there might be high exposure potential. However, the dynamic nature of nanomaterials throughout their lifecycle presents challenges for using physicochemical properties as predictors of biological behavior. Workshop participants identified the need for a set of screening tools to correlate the functional properties of nanomaterials—i.e., how they behave rather than what they are made of—to determine potential for bio-interaction. These tools do not exist today.

The second workshop, held at the Centre for Global Dialogue in Rüslikon, Switzerland in June, focused on the mechanisms by which engineered nanomaterials interact with biological organisms—including oxidative stress, inflammation and immune response, protein misfolding, apoptosis and necrosis, genotoxicity and mutagenicity, and developmental effects—and interactions between engineered nanomaterials and in vitro and in vivo systems at the level of biological molecules, target cells, tissues and whole animals. Workshop participants identified a need to understand what happens to a nanoparticle when it enters a biological organism and becomes coated with biomolecules in a complex and dynamic manner that is still poorly understood. Tools for characterizing these coatings, for tracking certain types of nanoparticles throughout the body, and for correlating cell-culture studies with impacts in whole organisms are all outstanding challenges.

Some themes that cut across both workshops were the need for standard terminology, a robust library of standard reference materials for use in nano-EHS research, a set of toxicology tools that have been validated for use with nanomaterials, and a better understanding of how dose and dose rate impact toxicity for nanomaterials. All these needs were seen as limiting the research community's ability to develop predictive models for the interactions of nanomaterials with humans and the environment.

The workshops were enabled by funding from the National Science Foundation (BES-0646107) with generous in-kind support from the National Institutes of Health and the Swiss Reinsurance Company. The final report is in preparation and will be made available at <http://icon.rice.edu>.