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EDITORIAL

Engaging stakeholders in nano-EHS risk governance

Jacqueline A. Isaacs · Carol Lynn Alpert · Matthew Bates · Christopher J. Bosso · Matthew J. Eckelman · Igor Linkov · William C. Walker

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Abstract We report on an unusually frank and wide-ranging discussion concerning nano-manufacturing environmental health and safety, between industry and government representatives, insurers and litigators, and experts in life cycle and risk analysis, held at the Boston meeting of the Sustainable Nanotechnology Organization in November 2014. By transitioning from a standard conference panel presentation with audience Q&A to a forum in which each of the two dozen stakeholders in the room was invited to briefly identify themselves and share their expertise and concerns, key understandings emerged along with more nuanced thinking about a broader range of factors influencing industry decision-making and investment, public perception, and government regulation. Industry representatives and advisors who had initially arrived at the session in "observer mode" spoke frankly about the dilemmas of pursuing innovative nanotechnologies with real potential for societal benefit in a climate of regulatory and legal uncertainty. This was a "conversation that has never happened before," noted one experienced participant, and it left many others hopeful that future stakeholder forums could accelerate the quest to achieve reasonable frameworks for safe governance of emerging technologies.

Keywords Nanotechnology · Stakeholder engagement · Alternatives assessment · Life cycle assessment · Risk · Nano-governance

J. A. Isaacs (✉)
Department of Mechanical and Industrial Engineering, Northeastern University, Boston, MA, USA
e-mail: j.isaacs@neu.edu

C. L. Alpert
Strategic Projects Department, Museum of Science, Boston, MA, USA

M. Bates · I. Linkov
US Army Engineer Research and Development Center, Concord, MA, USA

C. J. Bosso · W. C. Walker
School of Public Policy and Urban Affairs, Northeastern University, Boston, MA, USA

M. J. Eckelman
Department of Civil and Environmental Engineering, Northeastern University, Boston, MA, USA

1 Context: Fall 2014 SNO conference

Life cycle assessment (LCA) and risk assessment (RA) have both attracted significant interest in the EHS community as bases for decision-making concerning manufactured chemicals and nano-materials (Department of Health and Human Services 2013). While both methods address a similar scope of issues, they are often applied in parallel, and interaction between the communities is often limited. LCA addresses multiple emissions and multiple impact categories. Information about a given product is analyzed from the extraction of the necessary raw materials through the production process, use, and disposal (Williams et al. 2009). After the information is gathered, it is "characterized" to benchmark environmental impacts according to derived characterization factors (Rosenbaum et al. 2008) and then normalized to a "functional unit" that is intended to aid in drawing comparisons between products that perform similar functions but may have widely disparate manufacturing or use realities (Bauer et al. 2008). By contrast, RA employs a cluster of methodologies focused principally on determining the exposure risk, given the deleterious properties—the hazard—of the associated

substance(s) known or suspected to be associated with a vulnerable system (a human being or environment). RA tools are also useful for making specific recommendations on the most effective and cost-effective means to mitigate risks specific to particular chemical substances.

This paper summarizes discussions held at the 2014 Sustainable Nanotechnology Organization (SNO) Annual Conference, in particular, a culminating discussion among both LCA and RA practitioners as well as industry and regulatory stakeholders and advisors. Previous sessions had covered advances in applying LCA and RA to nano-materials, tackling many of the difficulties posed by their wide-ranging characteristics and properties, their size-dependent behaviors and effects, and the limited empirical/mechanistic understanding of nano-toxicities (Grieger et al. 2010, 384; Miseljic and Olsen 2014). The prior LCA session, for example, addressed specific methodological challenges to accounting for the enhanced and varied functionality of nano-materials, beyond mass-based analysis, and inclusion of use-phase benefits and end-of-life emissions of both nano and non-nano elements. These are standard considerations in LCA, but have been lagging in the literature to date, due in part to the prospective nature of many studies (Miseljic and Olsen 2014).

In the RA session, discussion had focused on advances in the development and application of a comprehensive new science-based RA framework for engineered nano-materials, followed by illustrative presentations on specific themes of exposures to ENM along the life cycle of nano-enabled products, ecosystems, and nano-toxicology. This framework builds on the landmark vision of the 2007 National Academy of Sciences report, Toxicity Testing for the Twenty-first Century: A Vision and a Strategy, which supports in vitro toxicity testing based on mechanistic injury pathways. The following challenges were identified: (1) the need for systematic integration of exposure assessment into hazard assessment and nano-toxicology; (2) comprehensive characterization of actual exposures along the life cycle of nano-enabled products; and (3) dosimetry consideration for the hazard assessment (in vitro and in vivo) (National Academies 2007).

The final joint RA/LCA session at SNO was organized to engage a range of stakeholders, particularly from manufacturing, government, and legal sectors, to broaden discussion beyond SNO's largely academic membership. The session's specific objectives included:

- Discussion of the relative utility of LCA and RA in making decisions on the environmental, health, and safety (EHS) effects of nano-manufacturing;
- Identification of concerns about nano-EHS governance facing individual clusters of stakeholders; and
- Development of strategies to align EHS policy to support sustainable nano-manufacturing.

Participants represented a broad cross-section of those interested in nanotechnology research, development, and commercialization. Attendees from government included retired NIOSH personnel, individuals from the Massachusetts Office of Technical Assistance (an agency that provides training and tools to help businesses comply with state regulations), the Massachusetts Department of Environmental Protection, the Massachusetts Toxic Use Reduction Institute, and the US Army Corps of Engineers (USACE). Industry perspectives came from representatives of Nanocomp Technologies, the Rogers Corporation, and Microfluidics. Consultants from Earthshift, Vireo Advisors, and Pixelligent attended. Also, representing private sector interests were attorneys from firms such as Prince Lobel, specializing in insurance and product liability litigation. The final stakeholder group was comprised of academic researchers, with participants from Northeastern University, Arizona State University, the University of Massachusetts Lowell, and the Netherlands Organization for Applied Scientific Research (TNO). A public engagement and science communication expert from Boston's Museum of Science also attended.

2 Framing and catalyzing the stakeholder discussion

The session began with three presentations on the decision-making process related to nano-materials from the perspective of three assessment frameworks: (1) RA, (2) anticipatory LCA—a combination of LCA, RA, and multi-criteria decision analysis that attempts to offer direct utility to policy and decision makers operating in an environment of uncertainty (Linkov and Seager 2011; Wender et al. 2014), and (3) alternatives assessment—a more general approach to making decisions about manufacturing or policy concerns that also can include LCA, RA, or other methods as needed (Lavoie et al. 2010). To guide the ensuing discussion, one of the session organizers proposed a framing question:

"The National Nanotechnology Initiative has leveraged considerable federal funding into nanotechnology research and development, and private investment has also been just as considerable, yet there is concern that the sector as a whole is mired within the so-called innovation "Valley of Death." What steps that can be taken to bring success, and/or metrics of success, to overcome this difficult phase of commercialization?"

The public engagement expert then asked participants in the room to each identify themselves and brief the group on their own stakeholder interests and concerns in the realm of nanotech commercialization. This call for active participant contributions to the discussion was well-received and catalyzed an unusually frank and wide-ranging

discussion that one participant described as "a conversation that has never happened before."

2.1 Stakeholder concerns

2.1.1 Government

Respondents from government agencies expressed varied concerns regarding nanotechnology governance that reflected respective agency missions. Agencies are challenged to balance concerns for safety with concerns for a realization of the nation's investment in nano-science and engineering research for societal benefit, in the absence of comprehensive information upon which to form those safety assessments. Commenters observed a recent groundswell of interest in "alternative testing schema" in response to the sheer magnitude of the demand for decisions about new substances, including nano-materials. Agencies hope to create a climate in which businesses can make socially, environmentally, and fiscally responsible decisions, in compliance with government requirements as well those of "good business practice" while at the same time confronting "emerging contaminants" and other potential risks posed by nano-materials amidst a dearth of actionable information on which to make effective policy.

2.1.2 Industry

Industry participants raised salient concerns. One theme that emerged was the difficulty that companies encounter when communicating with workers and with clients an appropriately nuanced picture of potential risks and hazards associated with nano-materials. Several participants shared anecdotes of workers and clients coming to them to request information that either does not yet exist or would do little to help them address the motivation for the request, like data sheets on a particular species of nanoparticle. Offers of what might be more relevant information (such as exposure risks) to the client or worker would be rebuffed, suggesting perhaps a lack of confidence in the manufacturer's expertise, confusion on current best practices for information on protection from exposure, a lack of trust in the manufacturer, or a perceived conflict of interest. These experiences suggest that there may be information gaps as to what factors are judged to be most relevant, and where individuals concerned about potential risks can go to gain greater context. Both over- and underestimation of actual risks can result.

Industry participants expressed weariness with the "presumption of guilt," the widespread perception of industry as a "likely bad actor," prevalent in many forums. They pointed out that established companies are not interested in rushing a product to commercialization and possibly producing the next "emerging contaminant." Most businesses and the people who run them want to play by the rules, provide useful goods and services, create jobs, and make reasonable profit. It's simply not in their interest to advance commercialization of a product in a climate of scientific or regulatory uncertainty, or even a perception of uncertainty that may lead to legal liability.

Industry participants also noted with frustration the fact that nanoparticles in products are hardly new—many have been in use for twenty or more years—and it is only relatively recently that the "nano-" prefix is of regulatory interest. The term "having the rug pulled out from under you" was mentioned more than once. Businesses rely on a sort of regulatory *stare decisis*—the norm that once policy is made, it is not changed except when the need is very great.

2.1.3 Insurance and litigation

Product liability and insurance litigation attorneys in the room highlighted the need to adopt appropriate but not draconian regulation and emphasized that the worst case for business may be the complete absence of regulation alongside the presumption that at some point, some regulation will be handed down. Industry representatives and their advisors attend meetings like this one partly because of the need to constantly monitor and anticipate new rules that may affect current and potential processes, products, investment, and innovation. Almost as frustrating are inconsistencies in regulation from jurisdiction to jurisdiction. A few attendees likened the situation to information security breaches: A company can be subjected to up to forty-seven different state-level procedures. Such regulatory fragmentation can be expensive, and even major corporations are loath to enter new markets under such conditions.

Participants recalled an earlier session on insurance for nano-products and companies, two panelists, an insurance industry professional and a product liability attorney, described the cycle that insurance products and the insurance industry go through time and again with novel technology where risks are suspected but not yet quantified. Generally, this process begins with coverage through Comprehensive General Liability insurance (CGL). Absent any explicit regulations or court decisions, the insurance industry must prepare to receive the brunt of any liability associated with a novel material or technology through this CGL coverage. However, once liabilities begin to be determined by the courts, insurers will begin a cycle of writing exclusions into policies. This cycle is widely anticipated to kick off at some point in the realm of nano-enabled products even if a particular judgment in a particular court lacks scientific consensus, because research into potential nano-material

hazards is still ongoing. In this scenario, there would be a period, yet to come, where firms engaged with nanotechnology would find themselves unable to obtain insurance coverage for their operations, or at least not without paying a hefty premium for it. Eventually, the insurance industry would develop specialized products to cover nano, while litigation irons out the last of those cases covered by old policies. As risk knowledge improves, insurance products would once again begin offering coverage for nanotechnology, with premiums scaled to actual—rather than speculative—understandings of risk.

Also from a product liability perspective, efforts to standardize labeling practices (e.g., by the International Standards Organization) as well as to perform alternatives assessment (e.g., under rules promulgated by the California Department of Toxics Substances Control) are relevant to potential litigation. In the absence of explicit regulation in a given jurisdiction, liability attorneys will seek to point out other regulatory practices in use elsewhere in the world, in other legal contexts, states, countries, wherever nanotechnology is being discussed. These practices will be brought into US courtrooms, even where it does not necessarily have legal bearing. Therefore, even in a market seemingly absent of any regulation, the courts can bring liability to bear.

2.1.4 Academic RA/LCA

Academic LCA/RA experts focused primarily on perceived choke points and forces at play in the systems that commercialize engineered nano-products as well as those that produce regulations affecting those products. These scholars ask, "What information do policymakers need?" and "What data would help form good policy?" Their work may help prioritize the EHS research and characterization efforts that need to be undertaken; however, it also is designed to guide assessments where data are more limited.

In this regard, an open question remains as to how much the "nano-" prefix facilitates effective regulation. Currently, US regulations proceed from the proposed function or action of a product (particularly in the context of food, cosmetics, and pesticides) because agency responsibilities are based on proposed functions more than on the nature of the materials. Feedback on this topic from the private sector representatives suggests that while the "nano-" prefix may not determine regulatory pathways, various agencies do react differently to nano-materials when it comes to enforcement or level of scrutiny, and a "nano-" prefix certainly can impact consumer concerns, either positively or negatively.

Whether or not there is actual regulatory significance to the "nano-" prefix, even the perception of a regulatory significance can be enough to dissuade investors and stymie commercialization. Investors want regulatory hurdles to be cleared swiftly. If this does not happen, they will take their risks—and their financing—elsewhere.

2.2 Traversing the Valley of Death

The original framing question for this session's post-panel discussion was to address getting nano-enabled technologies and products past the point where investment in research falls off, but where investment in commercialization has not yet begun (Government Accountability Office 2014). This is known as the "Valley of Death" in the cycle of a new product development. The discussion over risks, including investment, regulatory, liability, environmental, health, and safety, highlighted issues that may keep nanotechnology stuck in the valley for some time to come. However, some participants suggested that the more fundamental challenge might simply be that few compelling "killer applications" for commercial marketing of nanomaterials have yet been demonstrated. Where marketability *has* been demonstrated, it is being exploited.

An analogy was drawn to the semiconductor industry's road map for commercialization. Some discussion followed as to whether the National Nanotechnology Initiative's roadmap was an emulation, with an approximate consensus that the semiconductor industry's approach had been more comprehensive, while NNI's approach had focused almost exclusively on government activities to promote the nascent nanotechnology sector. In addition, several participants made the important distinction that nanotechnology is not a single industrial sector akin to semiconductors. Rather, nanotechnology refers to a capacity of engineering at smaller scale and thus can be considered inherent in every industrial sector that is pushing boundaries in the direction of "small." That nanotechnology is an "enabling technology" makes it more challenging to address with an overarching development strategy or regulatory policy. Since nanotechnology is not a single distinct product, we note here that the application of product development cycle theory to this "discipline" using the Valley-of-Death concept may be inappropriate.

Some industry representatives seemed optimistic that once viable commercial applications were identified, regulatory uncertainties would cease to present a significant barrier to commercialization. "Businesses will find a way," said one. Others suggested that federal and industry support for applied research was important to continue, along with further EHS research.

3 Closing thoughts

The frank views and perspectives exchanged in this final SNO session offered many "ah-ha" moments for participants, suggesting, in particular, that in conferences on governance of emerging technologies designed to attract relevant stakeholders and experts, it would be wise to limit the amount of time devoted to formal presentations of academic research and Q&A directed solely to the panel and instead encourage face-to-face discussion of key areas of concern, mining all of the expertise in the room.

Revelations that the absence of regulation can be as much of a hindrance to commercialization as too much regulation are important for the academic community as well as regulators and investors to understand, especially in a rhetorical environment that traditionally says otherwise. The value of stakeholder engagement was reinforced by this session, as was our sense that there must be ample room for more discussions like this one to help each of these respective communities develop closer ties to the others that will prove useful in making better decisions about nano-materials and the issues that surround them.

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