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NEWS AND OPINIONS

The challenges of nanotechnology risk management☆

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Summary Recent developments in the design of advanced materials have furthered interest in the commercialization of new technologies. Central to this rapid technology revolution is the consideration of the potential environmental, health, and safety (EHS) risks associated with nanomaterials. Risk assessment has been proposed as a primary method to evaluate EHS risk and decision making, where risk assessment practitioners seek to understand what can go wrong, its likelihood of occurrence, and the ultimate consequences if it should arise. Here, we outlined recent efforts geared toward risk assessment for nanotechnologies and nanomaterials, and discuss the challenges associated with providing accurate risk information to policymakers and regulators. Risk assessment that includes analytical approaches will provide decision makers with adaptive guidance regarding how to balance risks with technological benefits and costs, communicate those trade-offs, and change nanomaterial design toward sustainable nanotechnology.
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Introduction

Risk assessment has traditionally been thought of as the evaluation of what can go wrong, how likely it is to happen, and the consequences of it happening [1]. As a regulatory platform, risk assessment has been the guiding principle for the evaluation of environmental and product risks, including nano-enabled technologies [2]. In the case of chemicals and nanomaterials, risk assessment has historically relied on detailed, empirical data for exposure and hazard (e.g.,

☆ The thoughts and opinions expressed here are those of the individual contributors alone and do not necessarily reflect the views of the National Nanotechnology Initiative or the U.S. Federal Government.

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dose—response models, which describe the change in effect on a system caused by differing levels of exposure to a stressor over a certain exposure time). This method of risk assessment, referred to as a *bottom-up approach*, may not be effective in researching the risks of fast-evolving, modern materials and technologies, as evidence alone does not typically lead to a specific course of action. Objective-driven approaches, referred to here as *top-down methods*, rely on the acquisition of information and synthesis from decision makers to drive actions. Top-down methods can improve and expedite the risk assessment process by integrating technical information and expert judgment on an emerging technology with human perceptions and values, thus allowing stakeholders to assess the relative merits of multiple risk-reduction alternatives. However, an important remaining challenge is to determine how to integrate both bottom-up and top-down approaches to facilitate risk-informed decision-making [3].

The U.S. regulatory community and nanotechnology industry continue to assess validated and reliable science-based methods and tools to augment existing approaches for risk analysis and regulation of nanomaterials. Significant global efforts by government and private sector stakeholders to collect EHS risk information have resulted in a large volume of data concerning nanomaterial fate and effects. The value and application of this information to relevant policy makers has been the subject of multiple national and international efforts, including four workshops organized by the NNI in 2009—2010 [4]. Various stakeholder communities such as industry, workers, consumers, and non-government organizations need assurance that these novel materials are safe for use. Efforts by government decision makers and private sector stakeholders to collect EHS information have helped build a large volume of data concerning nanomaterial fate and effects. For example, federal agency approaches to risk assessment stress the importance of basing any risk decisions on the best available scientific data. Traditional *bottom-up approaches* to risk assessment include gaining information regarding the toxicity of a compound and determining limits for exposure and uptake into the body. Such research must be followed by the development of robust methods for characterizing and quantifying exposures to humans and to organisms in the environment [5].

In 2009, NNI agencies reviewed the 2008 EHS Research Strategy and the information and data in EHS and the ethical, legal, and societal implications (ELSI) arena to consider the best path forward for nanotechnology. The 2008 EHS Research Strategy document represented the culmination of a comprehensive effort led by the Nanotechnology Environmental and Health Implications (NEHI) Working Group under the National Science and Technology Council's Nanoscale Science, Engineering, and Technology (NSET) Subcommittee to provide guidance to the NNI Federal agencies producing scientific information for risk management, regulatory decision-making, product use, research planning, and public outreach. During this review, the 2009 nanotechnology EHS (nanoEHS) workshop series convened experts from industry, academia, and the United States Federal Government to share the latest information and newest developments, the current state-of-the-science, and research gaps in the nanotechnology-related EHS field [6]. For example, the NNI 2010 Capstone workshop [7] concluded

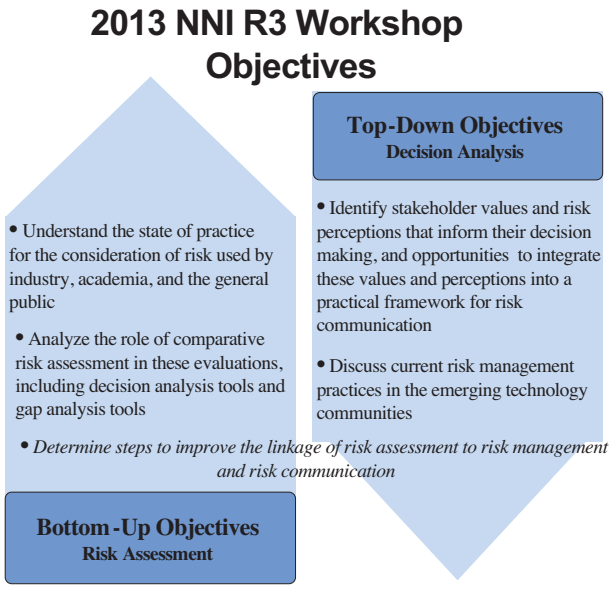

Figure 1 2013 NNI R3 workshop objectives.

that existing approaches to assess environmental risks of nanomaterials or establish standards are data-intensive, time-consuming, and expensive. Overall, the knowledge gleaned from the nanoEHS workshop series was critical to the development of the 2011 NNI EHS Research Strategy. This strategy document identified important data needs in the areas of nanomaterial measurement infrastructure, risk assessment and management methods, human health, the environment, informatics, and human exposure assessment.

As a follow up to the previously mentioned NNI EHS workshop series, the 2013 NNI nanoEHS stakeholder workshop[1] was designed specifically to facilitate discussion among various stakeholders of approaches, tools, and methods used to assess, manage, and communicate the potential risks of nanomaterials and nanotechnology-enabled products [8] (see Fig. 1). Approximately two hundred participants engaged in the workshop, including over a hundred participants on site and another hundred remotely. Participants included stakeholders from insurance companies, industry, labor organizations, academia, government, non-governmental organizations, and other members of the public. Stakeholder communities emphasized the importance of sharing the right amount of information to support *top-down approaches* for risk-based decisions on nanomaterials [9]. Participants discussed the importance of providing sufficient information on nanomaterial-containing products in safety data sheets in order to protect workers [10]. Input from the business community called for the development of best practices for agencies to communicate with small businesses. For example, stakeholders

[1] The NNI ''Stakeholder Perspectives on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology'' workshop, September 10—11, 2013.