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An Adaptive Framework for Managing Nanoscale Materials Risks

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Abstract

Given rapid development in the production and use of nanomaterials (NM), risk assessment is an important tool for assuring health and environmental protection. An adaptive risk assessment framework is being developed to provide an approach for precautionary decision-making. This step-wise approach integrates an evaluation of current toxicological information and sources of uncertainty about the specific NM of interest, identification of the potential exposure scenarios, and application of risk assessment concepts and tools to evaluate and prioritize management procedures for mitigating NM exposure risk. The adaptive approach allows new information to be incorporated as it is developed, to guide revision or refinement of health and safety recommendations for NM use and handling and for decision-making under uncertainty.

1. Information Need for Nanomaterials

Developments in nanotechnology and nanomaterials (NM) are rapidly proceeding ahead of a clear understanding of their potential health effects and environmental impacts. Risk assessment will be an important tool for evaluating and potentially regulating NM to protect health and the environment. We are developing an adaptive risk assessment framework for NM that provides an approach for precautionary decision-making and considers the current toxicological uncertainties about NM. Critical NM properties that contribute to the toxicological uncertainties include: a large surface area relative to NM size, their reactivity, and the possibility that NM may translocate within an organism. Our step-wise approach integrates an evaluation of current toxicological information and sources of uncertainty about the specific NM of interest, identification of the potential exposure scenarios, and application of risk assessment tools to evaluate and prioritize management procedures for mitigating NM exposure risk.

Our adaptive approach allows for input of new information about NM to revise and refine health and safety recommendations for NM use and handling and for decision-making under uncertainty. We combine elements of risk assessment with the practices of health and safety to provide relevant NM management procedures for minimizing potential health effects and environmental impacts. This approach offers an effective tool to evaluate potential NM impacts throughout their life cycle, ranging from research and development and product manufacturing, to consumer applications and uses, and ultimately to their disposal and fate in the environment. Identifying the key exposure pathways creates the opportunity to mitigate them, and to operate in a safer work environment. Understanding the environmental, health and safety risks allows effective management of them.

2. Products and Potential Health Implications

Most recognize that nanotechnology is at an early stage in the innovation cycle and that the potential for dramatic change in manufacturing, materials science, and the use of nanoscale materials is not yet realized. Hundreds of products are already on the market containing NM; hundreds of products are in development, and an even greater number are at the research stage. The promise of molecular manufacturing creates potential for dramatic shifts in the development and use of materials for industrial, consumer, and medical uses. The unique properties of NM are attractive for product development because they confer

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attributes such as conductivity, increased reactivity, light weight, improved strength, and self-cleaning surfaces compared to conventional materials. However, recent toxicology reports suggest that the same properties that make some NM attractive may also create biological activity and toxicity.

Currently, thousands of workers and an even greater number of consumers are potentially exposed to a wide variety of NM. Are they safe? What happens to NM as they enter the environment? Several research reports indicate that exposures by inhalation, dermal, and ingestion routes may lead to toxicity, including fibrotic formations in the lungs of mice exposed to carbon nanotubes, and toxicity following dermal exposure (Shvedova et al., 2003; 2005), and uptake of fullerenes across the gills of fish (Smith et al., 2007). Some evidence suggests that the results may be very dependent on the laboratory test conditions, and without adequate exposure information, the tests are difficult to interpret. For example, researchers at the Centre for Drug Delivery Research at the University of London's School of Pharmacy reported that carbon nanotubes functionalized to be water soluble were rapidly cleared from the blood and urine of injected animals (Singh et al., 2006). Certain water-dispersible forms of single-walled nanotubes (with more sidewall functionalization) were found to be less cytotoxic, which also suggests promise for drug delivery and diagnostics (Sayes et al., 2006)

3. Adaptive Framework for Assessing Risks of Nanomaterials

At this stage, it is reasonable to conclude that nanoscale materials have the potential to be toxic. What is unclear is how significant the potential for exposure may be because it is the exposure potential that drives health and environmental risks. Generating and reviewing the toxicology data constitutes a hazard assessment, that is, a process to characterize the potential hazards of a material. Many toxic materials in current use do not pose a risk to the user, due to low level exposures. However, hazard assessment does not consider all aspects of real world exposures. Risk assessment considers both toxicity and exposure when characterizing the potential for harm, and provides a more complete and informative result.

Risk is a function of both the toxicity of a material and exposure of an individual or population to it. Our risk-informed evaluation framework shifts the focus from hazard potential to risk, and considers how and under what conditions human and environmental exposure may occur. Exposure considerations include intended and unintended uses, and the potential for human and environmental exposure to nanomaterials and to products throughout the life cycle. Amid uncertainties about the biological and environmental attributes of nanoscale materials, defining and analyzing the key variables for exposure assessment focuses on potential areas of concern and control points. Risk analyses can inform the broad field of risk management of nanomaterials and nanotechnology.

Our approach for managing the uncertain risks of nanomaterials recognizes that new information will continue to become available in this rapidly evolving field. The development of risk science over the last decades has contributed to improved decision making under uncertainty. Health risk assessment has been applied to environmental concerns at hazardous waste sites, from drinking water exposures, in indoor and ambient air evaluations, for food safety, and in multimedia investigations of agents. Where limited data are available, quantitative assessments may not be plausible or informative. Analysis at a screening level, however, where assumptions are used as placeholders in the absence of available data, provides insights that can inform decisions.

The adaptive risk framework for nanotechnology allows critical and precautionary decision making under uncertainty. As new information develops, key assumptions are revisited, and risk estimates revised. The iterative process moves toward more detailed characterization of risks as the technical information is developed to inform it. The framework provides a structure for proactive and protective environmental health and safety decision making about nanotechnology in research, manufacturing, and consumer environments.

4. Looking Ahead

A critical element of our approach is identifying the unique properties and characteristics of each NM, its associated processes and uses, and how these processes and uses may create hazards and/or risks. The framework is designed to consider the toxicological uncertainties of NM, to allow for decision making under these uncertainties, and to provide relevant recommendations that incorporate health, safety, and environmental considerations. Importantly, this is an adaptive approach that allows for input of new NM information and revision of recommendations based on changes in knowledge or processes. Over time, improved understanding of toxicity and exposure will lead to refinement of the risk assessment. This adaptability also provides the opportunity to anticipate and plan appropriately for new NM and their processes.

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