A Framework for Responsible Nanotechnology

S. Walsh*, T. Medley**

*Environmental Defense, 1875 Connecticut Ave, NW, Washington, DC, 20009, swalsh@edf.org
**DuPont, 1007 Market Street, D-6074, Wilmington, DE 19898, Terry.L.Medley@USA.dupont.com

ABSTRACT

This presentation will focus on the draft Nano Risk Framework (hereinafter referred to as "the Framework") that Environmental Defense and DuPont have developed, available at www.nanoriskframework.com. We presented an overview of our concept for this framework at last year's NSTI conference. This year, we will present greater detail on the full framework, focusing on the new and different elements that distinguish this framework from other risk management frameworks.

Environmental Defense, an environmental advocacy organization, and DuPont, a science-based products and services company, have developed a comprehensive, practical, and flexible framework for evaluating and addressing the potential risks of nanoscale materials. The intent of this framework is to define a systematic and disciplined process for identifying, managing, and reducing any environmental, health, and safety risks of engineered nanomaterials across all stages of a product's lifecycle. Our framework offers guidance on the key questions an organization should consider in developing applications of such materials, and on the key information needed to make sound risk-evaluation and risk-management decisions. The framework allows users to move ahead despite areas of incomplete or uncertain information, by using reasonable assumptions and by compensating for knowledge gaps with appropriate risk-management practices. Further, the framework describes a system to guide information generation and update assumptions, decisions, and practices with new information as it becomes available. And the framework offers guidance on how to communicate information and decisions to key stakeholders.

We believe that the adoption of this framework can promote responsible development of nanotechnology products, facilitate public acceptance, and support the development of a practical model for reasonable government policy on nanotechnology safety. We have solicited and incorporated feedback on our overall approach from a wide range of international stakeholders, and we are now pilot-testing the framework on several materials and applications, at various stages of development. We expect that the framework itself will evolve as it is used by a variety of stakeholders in a variety of settings for a variety of applications. We welcome feedback that will help us to improve it.

Keywords: environment, health, safety, risk, guidance

1 INTRODUCTION

Nanotechnology, the design and manipulation of materials at the atomic scale, is a new area of knowledge that promises a dazzling array of opportunities in areas as diverse as manufacturing, energy, health care, and waste treatment. But while the ability to manipulate nanomaterials and incorporate them into products is advancing rapidly, our understanding of the potential environmental, health, and safety effects of nanomaterials — and of the most effective ways to manage such effects — has proceeded at a much slower pace. Given the enormous potential commercial and societal benefits that may come from nanotechnology, it is likely that nanomaterials, and products and applications containing them, will be widely produced and used. Therefore, it is especially important to understand and minimize the potential risks.

Environmental Defense and DuPont worked to develop a comprehensive, practical, and flexible system, the Nano Risk Framework, for evaluating and addressing the potential environmental, health, and safety risks of nanoscale materials. Further, the Framework is designed to act as tool to document and communicate the steps a user has taken to address those risks and the basis for those actions. We believe that the adoption of the Framework can promote responsible development of nanotechnology products, facilitate public acceptance, and support the formulation of a practical model for reasonable government policy on nanotechnology safety.

2 SCOPE AND INTENDED AUDIENCE

The intent of this framework is to define a systematic and disciplined process for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's "lifecycle" — its full life from initial sourcing through manufacture, use, disposal, and ultimate fate. Our framework offers guidance on the key questions an organization should consider in developing applications of nanomaterials, and on the information needed to make sound risk-evaluation and risk-management decisions. The framework allows users flexibility in making decisions by compensating for knowledge gaps with reasonable assumptions and appropriate risk-management practices. Further, the framework describes a system for guiding information generation and updating assumptions, decisions, and practices with new information as it becomes available. And the framework offers guidance on how to communicate information and decisions to key stakeholders.

3 NEW AND DIFFERENT ELEMENTS

Users acquainted with other risk-management frameworks will recognize some familiar elements here. Although we began this partnership without any preconceived opinions on whether nanoscale materials might require entirely new methods for evaluating and managing risks, we were pleased to find that the basic principles of many existing risk frameworks could be applied to our work. For example, this framework follows a traditional risk-assessment paradigm similar to the one used by the U.S. Environmental Protection Agency for evaluating new chemicals.

In addition to conserving some tried-and-true elements, we also hope with our framework to improve upon typical risk-management frameworks by incorporating several new or atypical elements. For example, it recommends developing informational profiles ("base sets") — relevant to the properties, hazards, and exposures associated with a given nanomaterial and its application — for evaluating risks and guiding decisions. In particular, we recommend developing lifecycle profiles that provide more information on physical-chemical properties, ecotoxicity, and environmental fate than has typically been the case. These additions are needed because of: a) the limited information and experience with nanomaterials for guiding decisions; b) the inability to predict or extrapolate risk evaluations based on limited information; and c) the importance of properties beyond chemical structure in defining nanomaterials' behavior.

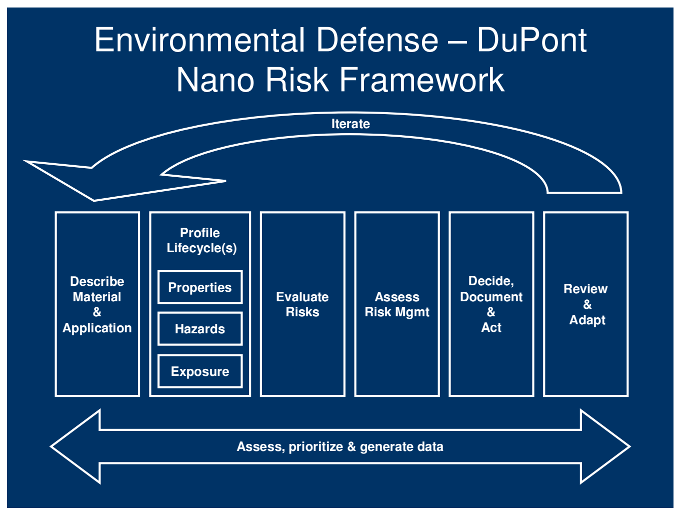
The framework is thus information-driven. The framework does not implicitly assume the risk or safety of any material. Where there is little or no information to guide decisions on the potential for a particular hazard or exposure, the framework suggests using "reasonable worst-case assumptions" — or, alternatively, using comparisons to other materials or processes that have been better characterized — along with management practices appropriate to those options. The framework is also designed to encourage replacing assumptions with real information, especially as a product nears commercial launch, and refining management practices accordingly.

In order for such a flexible framework to offer assurances to stakeholders, it requires transparency and accountability. Our framework is a tool to organize, document, and communicate what information the user has about the material; to acknowledge where information is incomplete; to explain how information gaps were addressed; and to explain the rationale behind the user's risk-management decisions and actions. Again, the iterative nature of the framework suggests that the amount of information a user shares with stakeholders may vary by stage of development. Though it is likely that less information will be shared at the early stages of development (when little is to be had), users should share enough information by the time of a product's commercial launch that stakeholders have a reasonable understanding of its potential risks and how they are to be safely managed.

The Framework includes an Output Worksheet, which is meant to facilitate evaluation, management, and communication. The Worksheet provides a template for organizing all the information requested by the framework, capturing overall evaluations of that information, and recording management decisions on how to act on it. The Worksheet can also be used as the basis for sharing information and decisions with stakeholders.

4 FRAMEWORK OVERVIEW

The framework consists of six distinct steps, and it is designed to be used iteratively as stages of development advance and new information becomes available.



Step 1. Describe Material and Application.

This first step is to develop a general description of the nanomaterial and its intended uses, based on information in the possession of the developer or in the literature. These general descriptions set up the more thorough reviews of the material's lifecycle properties, hazards, and exposures that are conducted in Step 2. The user also identifies analogous materials and applications that may help fill data gaps in this and other steps.

Step 2. Profile Lifecycle(s).

Step 2 defines a three-part process to develop profiles of the nanomaterial's properties, inherent hazards, and associated exposures. The properties profile identifies and characterizes a nanomaterial's physical and chemical properties. The hazard profile identifies and characterizes the nanomaterial's potential safety, health, and environmental hazards. The exposure profile identifies and characterizes the opportunities for human or environmental exposure to the nanomaterial — including exposure both through intended use and by accidental release. The user considers the nanomaterial's full lifecycle from material sourcing, through production and use, to end-of-life disposal or recycling. The user considers how the material's properties, hazards, and exposures may change during the material's lifecycle (for example, because of physical interactions during manufacturing or use, or chemical changes that may occur as it breaks down after disposal). The step suggests base sets of information, as well as the use of bridging information, to guide the development of these profiles. Various conditions (e.g., stage of development, type of use) will influence how fully a user may complete the base sets, or whether a user may incorporate additional information into the profiles. All three profiles work together — exposure information may suggest which hazards are most important to investigate, and vice versa; similarly, the material's properties may suggest which hazards or exposure scenarios are most likely.

Step 3. Evaluate Risks.

In this step, all of the information generated in the profiles is reviewed in order to identify and characterize the nature, magnitude, and probability of risks presented by this particular nanomaterial and its anticipated application. In doing so, the user considers gaps in the lifecycle profiles, prioritizes those gaps, and determines how to address them — either by generating data or by using, in place of data, "reasonable worst case" assumptions or values.

Step 4. Assess Risk Management.

Here the user evaluates the available options for managing the risks identified in Step 3 and recommends a course of action. Options include engineering controls, protective equipment, risk communication, and product or process modifications.

Step 5. Decide, Document, and Act.

In this step, the user consults with the appropriate review team and decides whether or in what capacity to continue development and production. Consistent with a transparent decision-making process, the user documents those decisions and their rationale and shares appropriate information with the relevant internal and external stakeholders. The user may also decide that further information is needed and initiate action to gather that information. And the user determines the timing and conditions that will trigger future updates and reviews of the risk evaluation and risk-management decisions for the nanomaterial or nanomaterial-containing product. A worksheet is provided in the appendix for documenting information, assumptions and decisions.

Step 6. Review and Adapt.

Through regularly scheduled reviews as well as triggered reviews, the user updates and re-executes the risk evaluation, ensures that risk-management systems are working as expected, and adapts those systems in the face of new information (e.g., new hazard data) or new conditions (such as new exposure situations). Reviews may be triggered by a number of conditions (development milestones, changes in production or use, or new data on hazard or exposure, for example). As in Step 5, the user not only documents changes, decisions, and actions but also shares appropriate information with relevant stakeholders.

Through these six steps, the framework seeks to guide a process for risk evaluation and management that is practical, comprehensive, transparent, and flexible.

5 FOR MORE INFORMATION

One of our main goals of developing this framework has been to do so in an open, transparent manner with other groups, companies and institutions who are also working to assess the potential risks and benefits of nano-materials. Since we began this project, we have solicited and incorporated input from a wide range of international stakeholders (large and small companies, government agencies, universities, and public-interest groups).

We would appreciate learning your reactions, thoughts, and ideas for making this framework even more effective for a broad audience. Your feedback will enable us to refine the framework to ensure that the final version - scheduled to be released this summer - is a user-friendly, comprehensive tool for businesses, governments, non-profits, university interests and others.

Please visit www.nanoriskframework.com to download the draft framework and provide us with your feedback.