Executive Summary

On June 14, 2005, a column titled "Let's Get Nanotech Right" appeared in the *Wall Street Journal.* Coauthored by Chad Holliday, chairman and CEO of DuPont, and Fred Krupp, President of Environmental Defense, the column outlined several commitments that society should embrace if we are to reap the benefits of nanotechnology's promise. In particular, it called for broad collaboration — interested stakeholders working together — to identify and address potential environmental, health, or safety risks. Less then three months later, Environmental Defense and DuPont entered into a partnership to develop a framework for the responsible development, production, use, and end-of-life disposal or recycling of engineered nanoscale materials — that is, across a product's lifecycle.

What follows is our proposal for a comprehensive, practical, and flexible Nano Risk Framework — a systematic and disciplined process —to evaluate and address the potential risks of nanoscale materials. The Framework offers guidance on the key questions an organization should consider in developing applications of such materials, and on the critical information needed to make sound risk evaluations and risk management decisions. The Framework allows users to address areas of incomplete or uncertain information by using reasonable assumptions and 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 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. We have also pilot-tested the Framework on several materials and applications, at various stages of development.

Users acquainted with other risk-management tools will recognize some familiar elements within this Framework. In addition, it incorporates several new or atypical elements. For example, it recommends developing informational profiles (or "base

sets") — regarding the properties, hazards, and exposures associated with a given nanomaterial and its application — for evaluating risks and guiding decisions. In particular, the Framework recommends developing lifecycle profiles that provide more information on physical-chemical properties, ecotoxicity, and environmental fate than has typically been the case in traditional risk management profiles.

The Framework is information-driven; it 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.

The Framework was designed to be flexible, but that flexibility comes with an obligation for users to be transparent and accountable in its implementation. Toward that end, the Framework serves as 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 justify the rationale behind the user's risk-management decisions and actions.

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 consequent management decisions.

Framework Overview

The framework consists of six distinct steps. It is designed for iterative use as development advances 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, in Step 2, of the material's properties, hazards, and exposures. The user also identifies analogous materials and applications that may help fill data gaps in this and other steps.

Step 2. Profile Lifecycle(s).

The second step defines a process to develop three sets of profiles — of the nanomaterial's properties, inherent hazards, and associated exposures throughout the material's lifecycle. 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. And 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 takes into account the nanomaterial's full lifecycle from material sourcing, through production and use, to end-of-life disposal or recycling. In so doing, 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 from chemical changes that may occur as it breaks down after disposal). The step suggests base sets of 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 — for example, exposure information may suggest which hazards are most important to investigate, or 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 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 so doing, 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 such 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, appropriate to the product's stage of development, 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 stakeholders, both internal and external. The user may also decide that further information is needed and initiate action to gather it. 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., regarding hazard data) or new conditions (such as new or altered exposure patterns). Reviews may be triggered by a number of situations (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.

The Framework, and case studies demonstrating its implementation on a variety of nanomaterials and applications, is available at www.nanoriskframework.com.