Approach to Breakout Discussion:

The purpose of the breakout sessions is to gather inputs on current tools, methods, and practice in risk-based decision-making (including NNI-funded activities). Participants will be asked to address **four thematic questions** (see bold questions on second page), based on their experience in their various roles in the development and use of nanotechnologies. Sessions will start with a brief presentation featuring a real-world case study followed by group discussion. Participants are encouraged to share as much real-world experience as possible, in line with the overall goal of this meeting to move beyond generic discussions on risk analysis and toward discussions of real-life situations and real experience(s) with identifying and navigating knowledge gaps.

A theoretical vignette is also offered as a tool to facilitate sharing feedback that might be otherwise constrained by confidential business information or limited experiences of some participants. It will also provide a way to achieve some consistency in the form of the feedback obtained from diverse breakout session groups. The vignette is not intended to place limitations on the discussion, but rather to act as a catalyst and an organizational guide.

Day 1 Breakouts: **The first day breakout will center on a "Type of Decision" from the perspective of various communities in their approach to the theoretical vignette (occupational risk analysis, commercial product life cycle, and environmental life cycle).**

Day 2 Breakouts: **The second day breakout will focus on "The Decision-Makers" by gathering inputs from each community in its approach to the theoretical vignette (research, regulatory, nanomanufacturing, small business, financial risk, NGO, and other public communities)**

Breakout Session Vignette

Nanoparticle X is a new nanoparticle that is being produced by several companies and added to drywall and paints to provide excellent energy-saving insulating properties. It is also being considered in food packaging to keep foods cold on the shelf and in blood bags to preserve donated blood. It is sold as a powder that is stirred into paint or added to thermoset polymers for packaging.
One rat inhalation study of a similar, but slightly different particle, found a considerable increase in lung tumors in exposed animals. Some companies have added a proprietary functional group to the particle or encapsulated the particles in an effort to minimize the compound's reactivity. The discrete nanoparticle is highly reactive, but becomes very stable in cured polymer matrices. Durability of its insulating properties reflects the properties of the matrix, so that it is potentially released when the end product degrades.

Considering your role with respect to risk-based decision-making, please share and discuss your answers to the following questions (next page). *Note:* Some secondary questions were provided for guidance *(in italic).* Participants are welcome to answer these *optional* secondary questions or answer newly generated questions under guidance from the session chairs.

Please remember:

- **Focus the discussion**: be concrete, use real-life examples, and keep in mind what is needed to move risk-based decision making forward.
- **Four overarching questions:** what risk-based information is needed, what tools/methods are available, how you make/communicate decisions, and how can the NNI help.
- **It is OK to have overlaps** with other groups (i.e., capture issues that are common across various breakout groups)

Assuming that risk will inform any decisions being made regarding the use and treatment of Nanoparticle X,

A. What types of risk assessment processes, if any, are being used in decisions about the commercialization/development/use of Nanoparticle X?

- *What decisions are you making that you would want to be informed by a risk assessment?*
- *What information from NNI would you use to initiate a risk assessment and secure resources for expediting the process?*
- *What factors affect your success and what is the timing of your efforts? (e.g., at R&D stage, after product development, commercialization)*

B. What are Tools/Approach/Models and Information Needed for Risk Assessments and Risk-Based Decision Making?

Please address each item with respect to what is available, how this work gets done (e.g. in-company, by consultants, in research consortia, etc.), how NNI work has made it possible, and where are the big questions and gaps.

- *What are tools and methods used for the risk assessment of materials such as Nanoparticle X?* (Note: please provide an overview rather than a laundry list of tools and methods)
- *What are the tools and methods that are used for integrating risk-based decision?*
- *How are Physical/Chemical Properties/Fate/Transformation assessed?*

C. How is Risk Information and Uncertainty Factored into the Decision?

- *In light of the tools/models you've discussed, how do you put risk information in a meaningful context, and how do you weigh this information against risk management options?*
- *When do you know there is enough information to make the risk decision? (What is the value of getting additional information?)*
- *How is uncertainty communicated to decision-makers? How to be sure it is understood and taken seriously?*
- *What tools are available to resolve uncertainties in risk and what factors determine whether or not to engage them (e.g. joint research, peer review, government regulatory action)?*

D. How can the NNI best support risk-based decisions?

- *Is the research being done focusing on the right questions, the right materials, the right analytical methods and scenarios?*
- *Are research findings rendered in the most accessible form?*
- *Are there other kinds of activities or information that NNI could support that would facilitate risk-based decision-making?*