Final
Meeting Summary Report
Risk Management Practices for Nanoscale Materials

(October 19 and 20, 2006 Meeting)

U.S. Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

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1.0 INTRODUCTION

This report summarizes the panel discussion and public comments during the public meeting on Risk Management Practices for Nanoscale Materials organized by the U.S. Environmental Protection Agency (EPA). The meeting took place in Washington DC, on October 19 and 20, 2006. Eastern Research Group, Inc. (ERG), a contractor to EPA organized the logistics, provided facilitation support, and prepared this summary report, which included review and comment for accuracy by EPA and panelists. Meeting minutes were not prepared and a transcript was not recorded. The intent of this report is to provide an overview of the discussion that occurred. No attempt has been made to analyze or evaluate any portion of the discussions. The discussion and comments presented in this summary reflect individual opinions of the commenters and should not be considered to be the opinion or belief of EPA.

1.1 Panel Members

- Dr. John Balbus. Senior Scientist and Director of the Health Program; Environmental Defense.
- Mr. James Cooper. Senior Manager, Government Relations; Synthetic Organic Chemical Manufacturers Association (SOCMA).
- Dr. Charles Geraci. Nanotechnology Research Center; and Chief, Document Development Branch; National Institute for Occupational Safety and Health (NIOSH).
- Mr. William Gulledge. Managing Director of the American Chemistry Council Nanotechnology Panel; American Chemistry Council (ACC).
- Dr Jacqueline Isaacs. Associate Director; Center for High-rate Nanomanufacturing (CHN), Northeastern University.
- Dr. Kristen Kulinowski. Executive Director for Biological and Environmental Nanotechnology (CBEN), Rice University.
- Dr. Andrew Maynard. Science Advisor to the Project on Emerging Nanotechnologies; Woodrow Wilson International Center for Scholars.
- Dr. Vladimir V. Murashov. Special Assistant to the Director; National Institute for Occupational Safety and Health (NIOSH).
- Mr. Sean Murdock. Executive Director; NanoBusiness Alliance.
- Dr. Loretta Schuman. Toxicologist, Office of Chemical Hazards (Nonmetals), Directorate of Standards and Guidance; Occupational Safety and Health Administration (OSHA).

- Mr. Ronald White. Associate Scientist, Deputy Director, Risk Sciences and Public Policy Institute; Johns Hopkins Bloomberg School of Public Health.

- Mr. Michael Wright. Director of Health, Safety and Environment Department; United Steelworkers of America (unable to attend).

1.2 Meeting Background and Purpose

As part of EPA's initiatives to address growing interest in the potential health and safety issues of engineered nanoscale materials (NMs), EPA is developing the voluntary Nanoscale Materials Stewardship Program (NMSP). This program is being designed to encourage responsible commercial development of NMs. The NMSP will also enable EPA, the affected industry, and interested stakeholders to enhance their ability to effectively and efficiently assess potential risks to human health and the environment from NMs and to identify risk management practices (RMPs) which may reduce such potential risks.

The NMSP may be structured to include two tiers: a basic program and an in-depth program. If this structure is adopted, participants will be given the opportunity to participate in either the basic or the in-depth program. In this scenario, the in-depth program would include all elements of the basic program, as well as the commitment to generate and report more information, and implement more in-depth risk management practices.

EPA held this public meeting to help support development of the NMSP by evaluating (1) the risk management practices that should be included in the Basic Program and (2) the additional risk management practices that should be considered in the In-Depth Program.

Prior to this meeting, EPA developed a discussion paper to outline key RMP information found in literature, present proposed elements of RMP to be included in the Basic Program, and present questions for consideration (appendix C). EPA then convened a panel to (1) review the discussion paper, (2) comment on RMPs that should be included in the NMSP, (3) discuss additional information on RMPs for NMs, and (4) summarize input for EPA to consider for finalizing RMPs to include in the NMSP. The panel provided individual comments and there was no attempt prior to, or during the meeting to arrive at joint decisions, reach consensus, or provide majority advice.

The meeting was organized into a series of sequential sessions over a two-day period. After initial introductions from EPA, an open, facilitated discussion occurred regarding the questions posed to panelists in the topical areas per the discussion paper. After panel members concluded their discussion, meeting observers were asked to provide comment. As time permitted, panelists then responded or continued discussion based on the public comments.

Additional information pertaining to the specific charge to panelists, a summary of their written responses prior to the meeting, and the meeting agenda can be found in the public docket and appendices of this report.

2.0 DAY ONE SUMMARY (OCTOBER 19, 2006)

2.1 Introductions

Nhan Nguyen (EPA; Office of Pollution Prevention and Toxics, Branch Chief, Chemical Engineering Branch). Mr. Nguyen greeted panelists and members of the public and offered a brief overview of OPPT's mission. He also discussed EPA's obligations pursuant to the Toxic Substances Control Act (TSCA) and various reviews and risk evaluations conducted by OPPT, particularly noting hazard and exposure assessments that must be completed to determine whether there is an unreasonable risk to workers, the general public, or the environment posed from the manufacturing, processing, and use of new and existing chemicals. This set the stage and context for why EPA is evaluating risk management practices in concert with other government agencies (e.g., OSHA and NIOSH). Mr. Nguyen also stated that the purpose of the meeting would be to solicit input from individual panel members and the public. EPA would then consider all input, but there would be no attempt during the meeting to come to consensus on any discussion topics.

Jim Willis (EPA; Office of Pollution Prevention and Toxics, Division Director, Chemical Control Division). Mr. Willis then provided opening remarks, including background on EPA's effort to evaluate potential human health and environmental risk that may be associated with nanoscale materials. Mr. Willis noted that EPA had established the voluntary Nanoscale Materials Stewardship Program (NMSP) and was soliciting input on its development during this meeting, per recommendations from the National Pollution Prevention and Toxics Advisory Committee (NPPTAC).

Mr. Willis commented that this meeting is the first in a series of public meetings to be held on a variety of related topics to help guide development and implementation of the NMSP; thereby, ensuring an open and transparent process. A second meeting pertaining to Materials Characterization is tentatively planned before the end of 2006 and a third meeting to identify and highlight pollution prevention (P2) benefits of nanomaterials is tentatively planned for the spring of 2007.

Jan Connery (ERG) facilitated the meeting. The panelists were first asked to briefly introduce themselves and comment on their interests in nanotechnology and reasons for participating on the panel. After introductions, Ms. Connery stressed to all participants and observers that there would be no attempt to reach consensus during the discussion. Rather, the intent of the meeting was to provide EPA with input from a broad stakeholder community on the various session topics. All comments and suggestions were to be recorded as individual opinions for EPA to consider while proceeding with development of the NMSP. However, to aid EPA's evaluation, the meeting summary document would note instances when multiple panelists concurred on any topic.

Scott Prothero (EPA; OPPT, Chemical Engineering Branch). Mr. Prothero gave a brief slide presentation summarizing EPA's request to panel members. This presentation focused on EPA's discussion paper and the corresponding questions for panelists that were distributed prior to the meeting (appendix C). In this discussion paper, EPA asked for input on six primary topics that pertain to risk management practices. The discussion paper presents the results of an EPA literature search to ascertain information on each topic, then requests input

regarding additional information and how the NMSP should be structured to encourage participation and fill appropriate data gaps. Mr. Prothero noted that a primary resource for EPA in identifying risk management practices to request input on was the NIOSH document *Approaches to Safe Nanotechnology: an Information Exchange with NIOSH*.

Mr. Prothero stated that the meeting today and tomorrow was organized to illicit an open discussion session regarding each topic. The floor was then turned back over the Ms. Connery for facilitation.

2.2 General Discussion

Ms. Connery asked each panel member to provide their general thoughts and comments on the NMSP, before delving into the detailed session topics.

Dr. Maynard began by commenting there is a good general framework for the program; however, it was difficult to provide comments on many portions of the discussion paper until additional specifics regarding program elements are established, noting that, "The devil is in the details." Dr. Maynard also commented he felt it was appropriate that NIOSH was the primary information source to date and that NIOSH should remain intimately involved with EPA's effort.

Dr. Maynard cited two specific points he felt would be important while developing the NMSP:

1. How uncertainty in data will be received and handled.

2. How EPA can provide "tools", instructions, and guidance to industry (focusing on small and medium-sized businesses that may not have appropriate resources).

Dr. Balbus commented he was pleased to see an emphasis on workplace exposures; however, he felt the NMSP should be expanded to explicitly include data gathering for down-stream, end uses of nanomaterials (NMs). He suggested that downstream users may have better (possibly first-hand) knowledge than the manufacturers regarding how nanomaterials are used. He suggested that EPA should consider outreach to these stakeholders to encourage them to participate as well. This includes requests for data and information during the industrial and consumer end uses as well as end-of-life waste handling and disposal of the NM. Mr. Balbus also expressed concern that the basic NMSP may not bring in meaningful NEW data if participants are only asked to provide information that is readily available (e.g., from a literature search).

Mr. Gulledge felt it was appropriate to begin with information from NIOSH efforts. However, he noted industry and others are conducting tests and acquiring data. Therefore, drawing conclusions from published literature may be premature at this time.

Dr. Kulinowski briefly introduced an ongoing study regarding risk management practices that are currently being used in industry. This study is essentially a voluntary survey that asks industry respondents to provide information on this topic. Results of the international

survey were scheduled to be released November 13, 2006. Dr. Kulinowski used this ongoing effort as an example of how various stakeholders need to coordinate efforts.

Dr. Murashov noted that NIOSH continually updates documents such as those used as the primary resource for EPA's discussion paper. He urged EPA (and other stakeholders) to continually monitor the NIOSH web site for updates and new information. Dr. Murashov suggested EPA consider developing a mechanism to systematically capture updates in the NMSP (possibly by direct links and references to NIOSH documents and activities).

Mr. Murdock added that an important issue is to clearly define terminology for all aspects of the NMSP. For example, he commented there is not one "nanomaterial industry". Therefore, he feels it is not appropriate to treat all nanomaterials in a similar manner, simply based on their size or structure. Rather, whenever possible each material should be evaluated on a case-by-case basis. Mr. Murdock then commented it is important to evaluate nanomaterials based on their form at the point of release and exposure. For example, many nanomaterials agglomerate into particles and may not be available for transport or uptake in the nano size regime.

Dr. Geraci echoed the importance of defining all terminology and nomenclature very early in EPA's program. He also suggested the program should be structured to include considerable flexibility because he does not expect a complete set of hazard data regarding nanomaterials to be available. Rather, he anticipates acquiring individual data points for multiple nanomaterials and attempting to extrapolate them to develop guidelines for analogous situations. Dr. Geraci also brought up the importance of developing education and outreach programs pertaining to good work practices. Finally, Dr. Geraci noted that NIOSH has established a voluntary partnership program with industry where NIOSH field research scientists and the facility staff work together to characterize nanomaterial processes, evaluate and measure worker exposure, evaluate and test various control procedures and work practices to minimize releases and exposures.

Mr. White complimented EPA's effort to "get ahead of the game with [the NMSP] program." He agreed with previous comments that the program should explicitly address the entire life cycle of nanomaterials. Mr. White also noted the program must determine how data gaps will be addressed. For example, how will EPA respond if a participating company recognizes they have no information on multiple requested data elements? Finally, Mr. White noted that whenever possible the program should make use of existing data regarding the hazards associated with current common nanomaterials (e.g. TiO_2). As appropriate, this information should be viewed as an underlying risk management approach for the entire program and should be used as a starting point for nanomaterial risk management practices for both the Basic and In-Depth programs.

Mr. Cooper credited EPA for convening an appropriate panel, with members of the scientific community, business, and other government agencies. He noted the importance of conserving resources and, "Not reinventing the wheel." Mr. Cooper agreed that defining terminology and standardizing approaches should be a key component of the program (and related EPA efforts). He also noted the need to prepare simplified guidance materials regarding the NMSP for participants (and industry in general). Mr. Cooper hopes that information from the program will ultimately be used to develop a "toolkit" for industry regarding management

practices. Regarding the inclusion of complete life cycle analyses in the NMSP, Mr. Cooper recognized this importance for an overall evaluation. However, he noted that chemical manufacturers (likely participants in the NMSP) may not know the industrial end uses for all their products. Therefore, it may be difficult for them to provide meaningful information.

2.3 Session 1: Proposed Approach and Elements for Risk Management Practices in NMSP Basic Program

Ms. Connery opened this discussion session by asking if the general approach for the basic program is appropriate, noting that EPA's vision is to be non-prescriptive when asking for data and information. For example, EPA's current view is to ask participants general information regarding the rationale used to evaluate potential risk management practices, what practices are in place, and any test data regarding the effectiveness of these practices.

Panel Discussion

Mr. Cooper (and Mr. Murdock) suggested that asking non-prescriptive and qualitative questions is appropriate. However, they cautioned EPA to be as clear as possible, otherwise each participant will interpret the request differently and EPA may get a data dump of all hazard and toxicity information at the facility.

Multiple panelists asked why EPA is leading this effort. During the ensuing discussion, various EPA personnel and panel members from NIOSH and OSHA provided responses to support EPA's involvement. Panelists representing NIOSH agreed with the need to gather more data on workplace risk management practices. In general, while actively involved in evaluating workplace exposures and the potential health and environmental concerns, NIOSH is strictly a research organization and does not have regulatory authority. However, NIOSH does have a mandate to conduct research and make recommendations on workplace hazards and risks associated with new technologies. Conversely, per TSCA, EPA does have an obligation to evaluate potential risk associated with domestic manufacturing, processing, and use of chemical substances. Further, EPA has regulatory authority to impart restrictions and/or safeguards to ensure there is not an unreasonable risk to workers, general population and the environment associated with industrial manufacturing, processing and use of chemicals. Other panelists mentioned that OSHA also has regulatory authority over workplace issues and that EPA and OSHA work together, while being supported by NIOSH.

Dr. Kulinowski commented that the basic program appears to be structured to compile existing information. She noted that new data is being accumulated every day; therefore, EPA should consider a mechanism to acquire and evaluate NEW data.

Dr. Murashov suggested adding a new item to the basic program to include development of a risk management toolkit (and possibly this could be an outcome of the program as an incentive for participation).

Dr. Maynard, Dr. Schuman and other panelists discussed their opinion that the program should reflect the hierarchy of risk management for protecting workers. For example, the program should imply the use of personal protective equipment (PPE) is only an appropriate

solution if engineering controls or process re-design to mitigate potential exposure are not feasible.

Dr. Maynard suggested including additional questions to explicitly request exposure measurements. Panelists discussed this suggestion, generally agreeing it is important and that development of a good risk management program at a facility should include specific data. However, most agreed that in lieu of data a qualitative approach to develop the facility's program should not be overlooked and may be appropriate.

Dr. Kulinowski suggested adding specific text to the questions stating, "Identification of hazard potential based on the facility's specific unit operations …must evaluate potential exposure points, then determine what needs to be done and why." Dr. Maynard concurred with the suggestion, noting the first step for a facility when developing a site-specific risk management program should be to evaluate the potential concerns, including exposure potential, rather than simply evaluating the hazards associated with chemicals.

Dr. Schuman commented that OSHA considers "worker training" and "work practices" to be separate topics. She suggested separating questions for these topics. Although not every panelist entered the discussion, there was general concurrence with this suggestion.

Dr. Geraci commented that it is unclear if EPA will ask for participation strictly from the nanomaterial manufacturer, or if formulators and end users will also be encouraged to provide information regarding handling of the nanomaterial. He suggested the downstream industrial users be included because this population of potentially exposed workers was much larger than the nanomaterial manufacturing population. Other panelists agreed while noting that the manufacturer may have information pertaining to primary customers, but may not have data for secondary or other downstream industrial users. Some suggested an outreach effort to include downstream users in the NMSP and at future meetings.

Mr. Gulledge agreed with EPA's philosophy to request information in a non-prescriptive manner.

Dr. Kulinowski noted that text of the current discussion paper specifically discusses nonoaerosols in multiple locations. EPA confirmed that there was no intention to limit any of the program elements to aerosols.

Public Comment and Q/A Session

Mark Banash (Zyvek) commented that all businesses consider worker safety and risk management during the development of any new process line. His company and colleagues throughout industry take these issues very seriously and would like to participate and share information as appropriate.

Patricia Casano (General Electric, member of NPPTC's Ad Hoc Work Group on Nanoscale Materials) offered points of clarification regarding the NPPTAC report. She noted that NPPTAC intended to suggest the basic program's primary function should be to collect available information, not requiring participants to implement any risk management practices.

Ms. Casano suggested that EPA clarify the intent of the basic program when soliciting participants.

Val Giddings (PrometheusAB) commented it is important to distinguish between potential hazards and risk.

James Nash (ORC World Wide) asked if the NMSP would be strictly voluntary in nature or if there would be regulatory components. Jim Willis (EPA) responded that the NMSP will be voluntary and is likely to continue for a minimum of two years. As information is gathered (from this and other efforts) EPA may identify concerns that require The Agency to consider regulatory options.

An observer requested that EPA emphasize the need for consistent nomenclature regarding nanomaterials. He also requested that EPA standardize the characterization methods and test procedures that will be acceptable for the NMSP.

Session Summary

Ms. Connery then summarized the primary discussion points from this session. These included:

- Panelists identified the need for hazard identification prior to development of site-specific risk management programs or general guidance. This will help prioritize areas for research and conserve resources.

- Most panelists agreed EPA should consider expanding the NMSP to include the complete life cycle of nanomaterials (industrial end uses as well as waste handling and disposal). They felt EPA should consider explicitly including these stakeholders in the NMSP and soliciting their input at future meetings.

- Some panelists suggested it is premature to provide guidance regarding appropriate waste management practices because appropriate hazard information is not available. Other panelists noted that it will require considerable time to acquire this information; therefore, qualitative information should be solicited (while not discontinuing efforts to acquire specific, quantitative data).

- Panelists suggested development of guides and a toolkit to assist NMSP participants in developing their site-specific risk management program, noting these should be living documents that will be continually reviewed for future modifications.

- Multiple panelists (and meeting participants) recognized the need for close collaboration among various government agencies and non-government stakeholders (i.e., EPA, OSHA, NIOSH, CPSC, etc.).

- Development of standardized terminology is important.

- NIOSH and ICON were in the process of data gathering efforts at this point (a critical step that will be continued). Regulatory authority for these kinds of activities was determined not be a factor due to its voluntary nature.

2.4 Clarification Remarks From EPA

Jim Willis (EPA) clarified EPA's preliminary thoughts and expectations regarding the NMSP and this meeting. Mr. Willis stated EPA recognizes the need to characterize nanomaterials while conducting an analysis of potential risk management practices. Therefore, EPA organized two public meetings: this meeting pertaining to risk management practices and a similar meeting focusing on material characterization (tentatively scheduled to occur before the end of 2006). EPA's intent is to solicit input on each topic and use it to formulate a better, more integrated design for the NMSP. Further, EPA's intent for these public meetings is to conduct them in an open, transparent manner; thereby, ensuring the entire stakeholder community can provide input.

Finally, Mr. Willis noted that EPA elected to take a non-prescriptive approach when drafting the NMSP elements. EPA's intention for this meeting was to provide a summary of current knowledge surrounding each program element as background. In addition, draft language for potential participants was provided. Individual comments from panelists and observers will be used to modify the specific design.

2.5 Session 2: Personal Protective Equipment (PPE)

Per the meeting agenda, the second session was devoted to discussion of PPE. However, the discussion paper and panel discussion was organized into two sub topics: respirators and protective clothing. The sub-sessions are summarized below.

2.5.1 Session 2a: Personal Protective Equipment (PPE) – Respirators

Ms. Connery asked the panel to discuss the specific questions posed in EPA's discussion paper (appendix C). First asking if there are additional information sources on the topic of respirators to consider; then, asking if the draft program elements EPA has proposed for participants of the basic NMSP are appropriate. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topic of respirators that EPA should consider?

Mr. White commented EPA should review and include OSHA's respiratory protection standard and OSHA's guidelines for the use of respirators, as appropriate.

Dr. Murashov stated the NIOSH respirator selection guide relies on occupational exposure limits, when available. Currently no limits exist for nanomaterials. However, he noted there is a draft limit for nanoscale titanium dioxide. Dr. Murashov noted that NIOSH will develop occupational exposure limits for other nanoscale materials when there is enough information to conduct risk assessment analysis.

Dr. Geraci noted that NIOSH has been asked to consider a project to evaluate the need for incorporating particle size into its respirator selection guidance, testing, and certification activities. NIOSH has already started a project to evaluate respirator performance in protecting against a nanometer-sized aerosol. He also noted a recent research report that is now on the NIOSH web site that demonstrated that several types of HEPA filters were efficient in capturing nanoparticles.

Mr. Gulledge referred to his written comments (appendix D), noting ACC is evaluating this topic and hopes to discuss preliminary results later this year.

Dr. Maynard and other panelists suggested that although there may be limited (or no) information regarding effectiveness of respirators for specific nanomaterials, there may be analogous data for fine particulates. For example, this includes data for welding fumes and viruses. Panelists recommended a "critical review" of analogous information that may be appropriate.

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Mr. White suggested explicitly including elements for processors [end users] of nanomaterials. He also suggested explicit text to include a description of worker activities involving nanomaterials.

Mr. Cooper recommended a more qualitative approach, asking participants to provide information on PPE in one consolidated block on the reporting form, rather than repeatedly asking for similar information (e.g., instead of asking for information regarding respirators in this section of the form, clothing later, engineering controls after that). He noted this may streamline the reporting form and encourage participation.

Dr. Kulinowski suggested EPA specify that The Agency's interest pertains to worker activities involving the nanomaterials. She also suggested explicitly determining whether EPA is asking for risk management information regarding the agglomerated nanomaterials (EPA may receive information regarding potential exposures, controls, PPE, etc. for agglomerates that are not of the nanoscale).

Although not all panelists entered this discussion, multiple panelists concurred and then used this as an example of the importance to define terminology such as "nanomaterials".

Dr. Balbus recommended adding an element to specifically ask what information or activities the facility had considered to determine if nano-aerosols may be generated.

Dr. Balbus also suggested clarifying text in multiple proposed elements to clearly state EPA's use of the term "internal" refers to facility-specific information.

Dr. Geraci noted many facilities require (or suggest) respirator use, "just in case", without a compelling scientific reason. To avoid EPA receiving misleading information regarding the frequency of appropriate respirator use, he suggested asking, "Why do you think a

respirator may be needed?" Then, asking the rationale for selecting a specific respirator, if one is used.

2.5.2 Session 2b: Personal Protective Equipment (PPE) – Protective Clothing

Ms. Connery again asked the panel to discuss the specific questions posed in EPA's discussion paper. First asking if there are additional information sources on the topic of protective clothing to consider; then, asking if the draft program elements EPA has proposed for participants of the basic NMSP are appropriate. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topic of protective clothing that EPA should consider?

Dr. Balbus noted that regarding penetration studies, some studies focus on penetration through clothing, gloves, etc., and others focus on penetration through skin. He suggested EPA clarify the request, and clearly distinguish between these types of analyses.

Mr. Murdock suggested EPA review information that has previously been submitted on Premanufacture Notification (PMN) forms.

Mr. White referred EPA to his pre-meeting comments for additional resources (appendix D).

Dr. Maynard again suggested evaluating data for analogous chemicals or materials in the nanoscale.

Dr. Schuman suggested a review of various papers from the Second International Symposium on Nanotechnology and Occupational Health (Minneapolis Minnesota; October 3rd – 6th, 2005). Dr. Maynard was familiar with these papers and suggested the completed studies may not be applicable or relevant. However, he noted ongoing studies that were introduced at the conference may be useful. Dr. Isaacs commented that at least one study that was discussed during the conference is still ongoing, and results may provide information in the future.

Multiple panelists engaged in a discussion pertaining to non-aerosolized nanomaterials. This includes penetration studies for nanomaterials that are in solution, dispersions, etc. Panelists cautioned that studies may be highly dependent upon the solvent and other components of liquid systems.

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Mr. Cooper noted that the elements and questions should include a consideration of the nanomaterial concentration and type of solvent (if appropriate). Although not all panelists entered the discussion, multiple panelists concurred, noting this information will influence penetration rates, potential uptake by the receptor, and risk evaluations.

Multiple panelists then discussed and elaborated on an earlier comment by Mr. Cooper. He suggested the current format of asking participants similar questions regarding multiple topics may appear daunting and excessive. He suggested reorganizing EPA's overall approach to streamline the questions and allow participants to qualitatively elaborate on their rationale for evaluating potential risk, developing a risk management program, and conducting monitoring studies (if they have conducted tests). He also suggested clearly noting EPA does not anticipate or expect that participants will have information for all topics because this may appear less intimidating and encourage participation.

Other panelists agreed with this concept in general, but cautioned EPA not to generalize the request at the expense of not requesting potentially useful information.

Multiple panelists also felt asking for techniques for measurements and testing, and the resulting test data may imply EPA expects companies to have data or to be developing it. Panelist felt this could be a deterrent to facilities that do not have this information (they may feel EPA expects them to have this information and do not want to call attention to themselves if they do not).

Panelists generally agreed EPA should stress there are no expectations that participants will have data, nor that they are required to generate new data (for the basic program). Rather, EPA should clearly state participants are asked to provide data they currently have.

Multiple panelists discussed another topic previously mentioned. They suggested EPA include information regarding resources to help participants develop an appropriate risk management program because this may encourage participation.

Public Comment and Q/A Session

Joyce Tsuji (Exponent) asked EPA to recognize that considerable resources are needed to conduct monitoring studies.

Pat Casano (GE) noted EPA could publicize the NMSP such that it includes research laboratories that may have conducted tests.

Session Summary

Ms. Connery then summarized the primary discussion points from this session. These included:

- Panelists noted PPE should be considered the last line of defense when developing a risk management program.

- Additional sources of information to consider include: OSHA's respirator guidance, recent NIOSH study regarding filter materials for respirators, results of several ongoing studies (e.g., those introduced at the Second International Symposium on Nanotechnology and Occupational Health),

and additional sources mentioned in pre-meeting comments from panelists.

- A critical consideration should be whether nanomaterials retain their nanoform during potential exposure and in the body (should agglomerates be considered?).

- Analogous data from fine particulates, viruses, fumes, etc. should be evaluated and considered.

- Multiple panelists suggested formatting the questions such that they are streamlined and less intimidating to potential participants.

- The nanomaterial concentration and solvent are applicable when assessing results and conducting a risk evaluation for mixtures.

- A distinction should be made between penetration through PPE and penetration through skin.

2.6 Session 3: Engineering Controls

Panelists were asked to discuss responses to the same two questions. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topic of engineering controls that EPA should consider?

Dr. Geraci stated that NIOSH currently has no reason to believe that nanoparticles will act differently regarding typical laws of fluid dynamics. Therefore, it is anticipated that theories surrounding the performance of current engineering controls will apply to systems associated with nanomaterials. He noted this general assumption is currently being investigated and verified through a series of laboratory and field studies (through partnerships with industry).

He noted that there was an early concern that nanoparticles would behave similar to gasses, but current information suggests their behavior is more similar to fine particulates.

Mr. White and Dr. Isaacs both referred to their pre-meeting comments for suggested resources (appendix D).

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Dr. Maynard suggested EPA ask participants to clearly indicate study results from laboratory tests vs. those from real world situations.

Dr. Geraci suggested that EPA may need to ask participants to thoroughly discuss their test protocol in order to evaluate the results. As a follow up, he noted participants may ask how to develop test protocol such that appropriate results can be obtained.

Dr. Geraci noted a recent NIOSH-funded study that evaluated the efficiency of HEPA filters for nanoparticles. The study evaluated 9 types of filter media using silver nanoparticles in the range of 2 to 20 nm. This comment resulted in considerable discussion that certain controls may only be effective for certain nanomaterials (i.e., this medium may only be applicable to Ag). Other chemical-specific factors such as electronic charges may affect results. Therefore, EPA may need to specifically ask participants if they considered using analogous data in the determination of engineering controls; and if so, were factors that could affect the performance of the controls considered.

Multiple panelists offered suggestions on how (or if) the NMSP should evaluate upset conditions (spills as well as startup and shutdown). Some panelists felt that spills should somehow be included in the NMSP, and if so they should be evaluated separately from "anticipated" releases (see Session 4, below).

Public Comment and Q/A Session

There were no public comments for this session.

Session Summary

Ms. Connery then summarized the primary discussion points and key information from this session. These included:

- Panelists recognized the importance of stressing the appropriate use of engineering controls when developing facility-specific risk management programs and when evaluating test results.
- Panelists again suggested streamlining the questions to participants in a less-intimidating manner.
- NIOSH is currently conducting field tests to evaluate a variety of engineering controls.

2.7 Session 4: Waste and Release Management (including spills)

Panelists were asked to discuss responses to the same two questions. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topic of waste and release management (including spills) that EPA should consider?

Mr. Cooper suggested emergency response coordinators may have additional information regarding releases of fine particulates.

Mr. White stated any discussion of spill cleanup should include guidance to avoid "energetic" approaches that would aerosolize fine particulates.

Dr. Maynard agreed and noted that cleaning up spills should be a separate topic because of non-typical situations. Multiple panelists agreed.

Mr. Cooper noted a need to get information regarding spills to all appropriate handlers (e.g., truck drivers).

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Dr. Balbus suggested that there should be another portion of the participant form that includes a discussion of end-of-life issues. He noted it may be appropriate to discuss end-of-life and waste handling along with accidental spills.

Other participants agreed this is important information, but suggested the nanomaterial manufacturer is unlikely to have knowledge on the end uses or the associated, potential accidental releases.

Still other participants suggested this may be appropriate, citing disposal companies and TSDFs (treatment, storage, and disposal facilities) as potential information sources.

Public Comment and Q/A Session

Joyce Tsuji (Exponent) provided two comments. First, she requested that EPA consider discharges and releases to water (not just releases to air). Second, she suggested there is some data on behavior regarding fate and transport of nanomaterials in water (no specific information was provided).

Debbie Bower (Brookhaven National Lab) commented they are currently conducting fate and transport studies. She also asked EPA to consider how to evaluate encapsulated nanomaterials.

Ms. Bower's comments resulted in considerable discussion regarding hazard characterization and whether it was appropriate to ask for risk management information before chemical-specific hazards were known.

Session Summary

Ms. Connery summarized the primary new discussion points and key information from this session. These included:

Panelists agreed discussions of anticipated and accidental releases should be separate topics.

Panelists suggested EPA note some important topics regarding expected and accidental releases when developing a risk management program, specifically, avoiding energetic cleanup practices.

Secondary, downstream industrial users and handlers of nanomaterial products (e.g., truck drivers) need additional guidance regarding potential spills.

2.8 Session 5: Worker Training and Work Practices

Panelists were asked to discuss responses to the same two questions. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topic of worker training and work practices that EPA should consider?

Multiple panelists commented that "worker training" and "work practices" should be separate topics.

Dr. Maynard referred to his pre meeting comments for specific references (appendix D).

Mr. Cooper did not provide additional information sources. He noted the lack of specific information, but an abundance of general information on these topics that may be appropriate for consideration. He suggested that EPA ultimately develop an information repository on risk management programs and guidance. Mr. Cooper recognized the resources needed to compile all information on this topic (and also recognized multiple organizations were currently conducting multiple studies). Therefore, he suggested EPA develop an Internet site that included links to resources, rather than the actual studies and information. Panelists were in complete concurrence with this suggestion.

Dr. Schuman noted the discussion paper correctly references OSHA sources regarding the use of respirators, but clarified there is a distinction between required and voluntary use.

Multiple panelists again discussed the potential of extrapolating data for one material to another, noting that chemical-specific situations may deem use of the analogous data inappropriate.

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Mr. Cooper suggested EPA should be more explicit regarding the type of information being requested. He commented that using the term "work practices" is too broad and participants may interpret this to mean everything at their facility. Other panelists agreed, noting this term could be redundant and confusing if already asking for information on PPE and engineering controls. Panelists again cited this discussion as an example for defining terminology (potentially in a glossary). Dr. Schuman noted OSHA has defined various types of work practices.

Mr. Murdock suggested EPA ask participants to explain their rationale for determining which workers required training.

Dr. Balbus suggested changing the draft text to specifically ask, "What training do you provide relative to nanomaterials …". Multiple panelists agreed with this suggestion.

Public Comment and Q&A Session

An observer suggested that EPA clearly state participants should provide all known information pertaining to handling of nanomaterials, not just information from a literature review.

Virginia Lee (EPA) noted OPPT has just established a nanotechnology web site: www.epa.gov/oppt/nano

Mark Banash stated his company and many peers have asked whether their customers implement worker training programs. His experience is that customers are either very cautious and implement rigorous training for nanomaterials, or they have no programs at all. His company feels morally (and legally) obligated to work with customers and educate them on safe practices for nanomaterials.

Session Summary

Ms. Connery summarized the primary new discussion points and key information from this session. These included:

- OSHA guidance regarding respirator use includes two categories: mandatory uses and voluntary uses.
- All panelists concurred with the recommendation for EPA to establish a web site that serves as a repository for links to information sources regarding risk management programs and practices.
- Panelists again noted EPA (and participants) should consider using analogous data, when appropriate.
- Panelists suggested adding a request that participants provide information regarding their rationale for who requires training.
- Panelists unanimously agreed the term "work practices" is too broad and needs further definition.
- Panelists unanimously agreed that terminology must be defined (a glossary was suggested).

3.0 DAY TWO SUMMARY (OCTOBER 20, 2006)

3.1 Session 6: Hazard Communication/Product Labeling/Customer Training

Panelists were asked to discuss responses to the same two questions. The discussion pertaining to each question is summarized below:

Question 1: Are there additional information sources on the topics of hazard communication/product labeling/customer training that EPA should consider?

Dr. Balbus suggested referencing "various public perception surveys", including those recently released by the Woodrow Wilson International Center for Scholars.

He also noted that Material Safety Data Sheets (MSDSs) may provide some information; however, they are not expected to include nanomaterial-specific concerns. This comment resulted in considerable discussion about information that is required in MSDSs and the potential of requesting participants to provide additional information as it applies to nanomaterials for future MSDSs.

Mr. Gulledge stated ACC is currently conducting a survey that focuses, in part, on the type of information companies provide in an MSDS.

Dr. Geraci stated NIOSH considers hazard communication and product labeling to be separate topics. He suggested separating these topics and clarifying the terms for participants.

Dr. Kulinowski agreed and specifically suggested clarification of "product labeling" is needed. Other participants agreed, specifically noting EPA should to clarify between consumer labeling and hazard communication labeling.

Mr. Murdock added that EPA may want to consider specifically discussing whether labeling includes development of new symbols for nanomaterials (this may be a future endeavor).

Dr. Kulinowski clarified (after considerable discussion on terminology) that ASTM has created 8 new terms for nanomaterials, but standardized chemical nomenclature has not been developed. She noted a press release on this topic is forthcoming.

Comments pertaining to nomenclature and standardized labeling resulted in discussions about developing classes or categories of nanomaterials. *Dr. Geraci* noted that NIOSH has been asked for an evaluation of what might be considered for appropriate, precautionary language and symbols for nanomaterials.

Dr. Maynard noted that hazard communication is typically based on the hazard of a substance, not the category of chemical ("What it does, not what it is"). Therefore, any language or other guidance should focus on the potential hazard, not simply because it is a nanomaterial.

Dr. Kulinowski stated ICON is attempting to develop classes of nanomaterials. The first workshop on this topic will be held at the National Institutes of Health (NIH) in January 2007.

Dr. Kulinowski stated ICON is conducting a survey that shows there are companies that have developed nanomaterial-specific training. Therefore, questions on this topic are appropriate and may provide information.

Question 2: Are the proposed draft, basic program elements and questions appropriate?

Mr. Cooper stated he believes the questions for this topic are too general and need further clarification. He suggested more specific questions, defining terminology, and specifically asking for information on the hazardous communication, labeling, and training that is specific for nanomaterials.

Dr. Murashov suggested asking participants about background information used in developing their hazardous communication, labeling, and training programs.

Multiple participants agreed with a suggestion to ask for MSDSs.

Mr. White commented that he believes the current and anticipated near-term lack of toxicity and hazard risk data for most nanomaterials suggests that a more precautionary and generalized approach will need to be applied to the content of haz-comm, product labeling and customer training compared to traditional practices for chemicals.

Public Comment and Q&A Session

An observer suggested asking about consumer labeling.

This comment elicited an extended discussion about what was appropriate to ask participants of the NMSP. For example, should chemical manufacturing participants be asked to provide information on labeling of a consumer product significantly downstream in the nanomaterial life cycle?

Follow-up comments addressed the overall NMSP program requirements.

Multiple Panelists suggested EPA must clarify whether participants are simply asked to provide information, or if they are also expected to implement a risk management program. Multiple panelists felt it was appropriate simply to ask participants to provide available information for the basic program. However, some panelists felt the integrity of the NMSP would be compromised (at least from the public perspective) without assurances that participants are implementing responsible practices.

Ward Penberthy (EPA) clarified that the primary goal of the basic program is to ask for information.

Session Summary

Ms. Connery summarized the primary new discussion points and key information from this session. These included:

- EPA must clarify terminology, particularly for labeling.
- EPA should consider asking participants for MSDSs, and for rationale if they provide nanomaterial-specific information.
- EPA should consider addressing hazard communication, labeling, and customer training as separate topics.
- Additional information sources to consider for these topics include: Wilson Center public perception surveys, ongoing ICON surveys, internal NIOSH-suggested language for MSDS and/or other labeling
- EPA should clearly define the basic program goals and requirements for participation.

Additional Question(s)

Panelists were asked an additional set of questions in this session:

- Are there examples of haz-comm, product labeling, or customer training for NMs?
- If so, what aspects of these examples for NMs differ from similar examples for non-NMs?
- Are there other aspects of haz-comm, product labeling, and customer training—beyond traditional practices—that should be considered or implemented for NMs?

Mr. Gulledge began a discussion between multiple panelists by suggesting the basic NMSP program should be very non-prescriptive and should not require participants to implement any elements of a risk management program at their site. He suggested it should simply ask for information on what they do, and ask them to consider various risk management practices.

Mr. Murdock commented that he felt EPA should not request participants of the basic NMSP program to provide information on the downstream industrial uses or the end-of-life management practices. He suggested that may be overly burdensome and might limit participation. Mr. Murdock suggested this information could be requested for participants of the in-depth program.

Dr. Balbus followed this discussion stating that at a minimum, EPA should add explicit text to ask for end use information for the in-depth program (if not asked for in the basic program). Some other panelists agreed with this suggestion.

Mr. White suggested updating all language in the program requests from "nano aerosols" to "nanomaterials".

Mr. Cooper noted that EPA should clearly state participants will not be required to, "live up to an acceptability standard" based on their submitted information. He is concerned that potential participants may feel EPA will evaluate their site-specific risk management program (or lack thereof) and deem it to be inadequate. The potential of "failing" this evaluation may deter participation. Other panelists agreed with this general concept; however, some panelists suggested EPA should implement an evaluation process for the in-depth program participants.

Mr. Gulledge again introduced the idea that EPA could develop a tool kit to help guide participants to information regarding appropriate risk management. The tool kit could also contain information on how to plan and conduct monitoring studies that may be requested for participation in the in-depth program. This may be an incentive to encourage participation. Multiple panelists concurred, and again suggested EPA could develop a web site that guides participants to additional information sources.

Dr. Geraci informed the group that NIOSH is just beginning a project to develop a tool kit for work place hazards. The primary audience is expected to be developing countries and the tool kit may not focus on nanomaterials; however, components of the tool kit may be useful if EPA decides to pursue this suggestion.

Public Comment and Q/A Session

An observer encouraged EPA to finalize the NMSP structure for both the basic and in-depth programs as soon as possible. This sentiment was reflected by a number of subsequent meeting observers and panelists.

An observer noted that EPA needs to develop and promote incentives that will entice participation in the NMSP. This comment initiated a discussion between panelists (and observers) regarding the importance of good incentives and an outreach program that will maximize participation.

Robert Reish (DuPont) asked EPA to clarify whether participation in the NMSP is intended to be facility-specific or corporate-wide.

Session Summary

Ms. Connery summarized the primary new discussion points and key information from this session. These included:

- Multiple panelists asked EPA to provide as much information to participants as possible. This could take the form of a tool kit and/or a

web site that serves as a repository for information sources. NIOSH recently initiated a project to develop a potentially-applicable tool kit.

- Panelists and observers requested EPA to develop appropriate incentives to maximize participation in the basic and in-depth programs.

3.2 Session 7: Considerations for Risk Management Practices in the In-depth Program

Ms. Connery introduced this session noting by that the discussion should now shift from specific elements to thoughts pertaining to additional requests for the in-depth program. It was noted that EPA is just beginning to formulate ideas for the structure of the in-depth program. The primary difference between programs is that EPA is likely to ask participants in the in-depth program to acquire new information and/or data. Although this could require participants to conduct literature searches, studies, or monitoring; EPA did not present a preconceived or prescriptive type of required information.

Discussion Question

After the general introduction, Ms. Connery asked panel members to comment on whether the bullets in EPA's discussion paper were reasonable to characterize the in-depth program (repeated below for reference).

- Focus on more limited number of nanomaterials;
- Generate and report in-depth information that allows EPA to conduct more complete, detailed risk assessment of identified nanomaterials and associated uses;
- Focus on identifying representative nanomaterials for testing, risk mitigation technologies, and related research;
- For each volunteered material, Basic Program information submitted while concurrently generating in-depth program elements (the latter may take time);
- In-depth information could be developed on key nanomaterial elements—including material characterization, human health hazard, environmental hazard, environmental fate, release and exposure, and exposure mitigation; and,
- Volunteers work to extend application of protective risk management practices identified by EPA along their supply chains, and to monitor workplaces, environmental releases, and worker health.

Dr. Maynard initiated the discussion by emphasizing that there should be no differences in the risk management practices that are utilized by participants in the Basic Program versus the In-Depth Program. Good occupational hygiene should be required in all

facilities regardless of their level of participation. He cautioned against giving the impression that there could be two levels of concern.

Mr. Cooper suggested the last bullet needs revision such that it explicitly encourages a stakeholder process throughout the supply chain. He noted that implementation of the in-depth program (as described) will require input from all industrial users, not just the nanomaterial manufacturers.

Mr. Cooper also suggested that EPA coordinate with similar efforts in Europe to acquire risk management information (specifically noting efforts by the Organization of Economic Cooperation and Development, OECD).

Mr. Gulledge requested that EPA clarify how far down the supply chain each participant was responsible for. For example, would EPA expect a chemical manufacturer to provide information regarding each end use?

Dr. Kulinowski stated EPA should develop a mechanism to make information publicly available. She believes this is a very important component that will enhance utility of the information (recognizing CBI concerns) and encourage public trust. Multiple panelists agreed.

Mr. Cooper suggested developing a mechanism for participants to form consortia.

Mr. Gulledge asked EPA to evaluate two similar European efforts and coordinate the in-depth NMSP with them as appropriate: OECD (discussed above) and REACH when that program is finalized.

Dr. Balbus stated that the unit operations and potential hazards will vary significantly between participants and it is probable that the type of information that is relevant between participants will also vary significantly. Therefore, it may be difficult to prescribe a generic set of requirements for participation in the In-Depth Program. He suggested that EPA consider working with participants on a case-by-case basis to develop customized participation requirements.

Multiple panelists discussed the wide differences in potential hazards between specific nanomaterials. This may require EPA to prioritize the type of information requested. If no prioritization occurs, participants may expend significant resources to acquire information that is not the primary concern. Mr. Gulledge noted ACC is preparing a matrix of current work that addresses end-points of concern for nanomaterials.

Multiple panelists again discussed the suggestion to require known information for the basic NMSP, while the In-Depth NMSP should require development of <u>new</u> information. Multiple panelists also reiterated the suggestion that the In-Depth Program could include some type of EPA evaluation of the submitted data.

Public Comment and Q/A Session

An observer asked EPA to consider forgoing the In-Depth Program in light of OECD's similar effort.

Session Summary

Ms. Connery summarized the primary new discussion points and key information from this session. These included:

- Panelists commented that EPA should consider requesting known information in the Basic NMSP while participation in the in-depth NMSP should require development of additional information.
- Multiple panelists agreed that EPA should prioritize the data gaps and target information requests for the in-depth program to fill the gaps of greatest concern.
- Multiple Panelists agreed EPA should encourage all members of the supply chain to participate.
- Panelists noted similar European efforts and suggested EPA should coordinate with OECD and the REACH program.
- Panelists agreed that an element of the In-Depth Program should not be to require more stringent RMPs than something expected for non-participants (ideally, every facility would implement an appropriate risk management program, regardless of participation in the NMSP).

3.3 Closing Remarks

Ms. Connery asked each panelist to reflect on the discussions throughout the meeting and state the topics of primary concern from their perspective (the most important take home points for EPA). Each panelist's points are briefly listed in the summarized bullets below (referring to more detailed notes throughout this report).

Dr. Kulinowski

- Data should be made publicly available.
- EPA should coordinate with other efforts to ensure global harmonization.
- EPA needs to adopt standardized terminology (rather than creating new terms unconnected to standard terms) and clearly define it for all participants.

Dr. Balbus

- The NMSP should include downstream industrial and consumer uses as well as end-of-life disposal.

Dr. Isaacs

- EPA should coordinate and harmonize with other efforts.
- EPA should coordinate with NIOSH as much as possible, because resources may be a concern.

Dr. Murashov

- Dr. Murashov concurred with the previous statements, particularly regarding coordination with NIOSH.

Dr. Geraci

- Dr. Geraci concurred with the previous statements, particularly regarding coordination with NIOSH.
- EPA should consider use of analogous data as appropriate.

Mr. Cooper

- EPA should coordinate with NIOSH and OSHA.
- EPA should coordinate with OECD.
- EPA should not underestimate the logistics and associated resource requirements of HOW participants will acquire and submit information. This could be a disincentive.
- EPA should develop and promote incentives.

Mr. White

- Mr. White concurred with previous statements.
- The NMSP should include downstream industrial and consumer uses as well as end-of-life disposal.
- EPA should prioritize the data gaps and request appropriate information only for the in-depth program.

Mr. Murdock

- EPA should clearly elaborate the program requirements ("terms of engagement").

Dr. Maynard

- Dr. Maynard concurred with previous statements.
- Dr. Maynard stressed the urgency of initiating the program.
- EPA should clarify and publicize the program goal(s). This will encourage participation.
- EPA should coordinate with NIOSH.

Dr. Schuman

- Dr. Schuman concurred with previous statements.

Appendix A

FR NOTICE

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) invites all interested persons to nominate qualified individuals to serve a three-year term as members of the National Drinking Water Advisory Council (Council). This 15-member Council was established by the Safe Drinking Water Act (SDWA) to provide practical and independent advice, consultation, and recommendations to the Agency on the activities, functions, policies, and regulations required by the SDWA. The terms of four (4) members expire in December 2006. To maintain the representation required in the statute, nominees for the 2007 Council should represent State and local officials concerned with public water supply and public health protection (2 vacancies) or represent the general public (2 vacancies). All nominations will be fully considered, but applicants need to be aware of the specific representation needed as well as geographical balance so that all major areas of the U.S. (East, Mid-West, South, Mountain, South-West, and West) will be represented. **DATES:** Submit nominations via U.S. mail on or before November 15, 2006.

ADDRESSES: Address all nominations to Daniel Malloy, Designated Federal Officer, National Drinking Water Advisory Council, U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water (Mail Code 4601–M), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460.

FOR FURTHER INFORMATION CONTACT: Email your questions to Daniel Malloy, Designated Federal Officer, *malloy.daniel@epa.gov* or call 202–564–1724.

SUPPLEMENTARY INFORMATION:

National Drinking Water Advisory Council: The Council consists of 15 members, including a Chairperson, appointed by the Deputy Administrator. Five members represent the general public; five members represent appropriate State and local agencies concerned with public water supply and public health protection; and five members represent private organizations or groups demonstrating an active interest in the field of public water supply and public health protection. The SDWA requires that at least two members of the Council represent small, rural public water systems. Additionally, members may be asked to serve on one of the Council's workgroups that are established on an as needed basis to assist EPA in addressing specific program issues. On December 15 of each year, some members complete their appointment. Therefore, this notice solicits nominations to fill four vacancies with terms ending on December 15, 2009.

Persons selected for membership will receive compensation for travel and a nominal daily compensation (if appropriate) while attending meetings. The Council holds two face-to-face meetings each year, generally in the spring and fall. Conference calls will be scheduled if needed.

Nomination of a Member: Any interested person or organization may nominate qualified individuals for membership. Nominees should be identified by name, occupation, position, address and telephone number. To be considered, all nominations must include a current resume, providing the nominee's background, experience and qualifications.

Dated: September 27, 2006.

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. E6–16380 Filed 10–3–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2004–0122; FRL–8070–3]

Risk Management Practices for Nanoscale Materials; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is convening a public meeting on risk management practices under a possible stewardship program for nanoscale materials under the Toxic Substances Control Act (TSCA). EPA is considering development of a stewardship program for such nanoscale materials. This program is being explored to encourage responsible commercial development of nanoscale materials. The stewardship program will also enable EPA, affected industry, and other stakeholders to build the capacity to assess potential risks to human health and the environment from nanoscale materials and to identify risk management practices available to reduce such potential risks. EPA is requesting comments at the public meeting on: Risk management practices currently used or potentially available for use for nanoscale materials, the rationale for the use of these practices and the effectiveness or efficiency of these practices, and issues to consider for including risk management practices for nanoscale materials in the stewardship program. These comments will inform EPA on risk management practices to include in the stewardship program.

DATES: The meeting will be held on October 19, 2006, from 8 a.m. to 5 p.m., and on October 20, 2006, from 8 a.m. to 2:30 p.m.

Comments must be received on or before 8 a.m., October 19, 2006.

Requests to present oral comments must be submitted to the technical person listed under **FOR FURTHER INFORMATION CONTACT** before October 16, 2006. Time for oral comments may be limited, depending on the number of requests received.

Requests to attend the meeting may be submitted electronically through the Eastern Research Group (ERG) registration website at *https:// www2.ergweb.com/projects/ conferences/nano* by October 16, 2006. Advance requests will assist in planning adequate seating; however, members of the public may attend without prior registration. Requests for special accommodations may also be submitted through the ERG registration website by October 16, 2006.

ADDRESSES: The meeting will be held at the L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024.

Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2004–0122, by one of the following methods:

- *Federal eRulemaking Portal*. *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2004–0122. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2004–0122. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http:// www.regulations.gov*, including any personal information provided, unless the comment includes information

claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket, EPA Docket Center (EPA/DC). The EPA/DC suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/ DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Room Number 3334) in EPA West, located at 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. EPA visitors are required to show photographic identification and sign the EPA visitor log. Visitors to the EPA/DC Public Reading Room will be provided with an EPA/DC badge that must be visible at all times while in the EPA Building and returned to the guard upon departure. In addition, security personnel will escort visitors to and from the new EPA/DC Public Reading Room location. Up-to-date information about the EPA/DC is on the EPA website at *http://www.epa.gov/epahome/ dockets.htm*.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Scott Prothero, Economics, Exposure and Technology Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8514; e-mail address: *prothero.scott@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to those persons who manufacture, import, process, or use nanoscale materials that are chemical substances subject to the jurisdiction of TSCA. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (NAICS code 325), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.
- Petroleum and coal product industries (NAICS code 324), e.g., persons manufacturing, importing, processing, or using chemicals for commercial purposes.

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may have an interest in this matter. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit CBI to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

Nanoscale materials are chemical substances containing structures in the length scale of approximately 1 to 100 nanometers, and may have different molecular organizations and properties than the same chemical substances in a larger size.

EPA is considering a stewardship program pertaining to these nanoscale materials. (See the **Federal Register** of May 10, 2005 (70 FR 24574-24576) (FRL–7700–7.) Information derived from the stewardship program would allow EPA and the affected industry to better understand the issues with respect to potential risks and for EPA to gain experience in the evaluation of such types of chemical substances.

EPA has received input from the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) regarding the intended outcomes of a voluntary program in the form of an Overview Document (Ref.1). The

Overview Document indicates that the program should:

1. Give EPA and the public a better understanding of the types of nanoscale materials produced in the United States. Characteristics of these materials that should be identified include: Physical, chemical, hazard and exposure characteristics; production volume; and the uses of the materials.

2. Help EPA develop a capacity and process for identifying and assessing risks of engineered nanoscale materials.

3. Help EPA determine what information it needs about engineered nanoscale materials and articulate those information needs to industry and other stakeholder groups.

4. Help EPA understand what risk management practices are being employed during production, processing, use and disposal stages, and what additional risk management practices should be considered for implementation.

5. Prompt or reinforce the implementation of risk management practices.

6. Provide the information and experience needed to develop an overall approach to the treatment of nanoscale chemical substances under TSCA that builds public trust in nanoscale materials while enabling innovation and responsible development. The Overview Document indicated that participants in the program should implement basic risk management practices or other environmental or occupational health protection controls (e.g., worker training, hazard communication (including Material Safety Data Sheet (MSDS)), use of available engineering controls, provision of personal protective equipment, product labeling, customer training, waste management practices, etc.). The Overview Document also suggested that, in developing the program, EPA should hold one or more public peer consultation meetings. Among other issues, the meeting(s) would address risk management practices to be included in a basic program and in an in-depth program, each offered under the overall program (Ref. 1).

EPA is holding this public meeting to assist in elaborating possible risk management practices for the stewardship program. The public meeting will involve panel discussions of EPA's discussion paper on possible risk management practices for the basic program, with time allotted for public comment. EPA will place in the public docket and the ERG registration website the discussion paper on possible risk management practices for nanoscale materials as well as an agenda for the meeting.

III. Issues for EPA and Stakeholders

EPA is requesting comments on the following risk management practices for nanoscale materials:

1. Worker training, including work practices.
2. Hazard communication.
3. Engineering controls.
4. Personal protective equipment.
5. Product labeling.
6. Customer training.
7. Waste management and environmental release management.

Comments in these specific areas will be particularly helpful:

- Risk management practices currently used for nanoscale materials.
- Risk management practices that could potentially be used for nanoscale materials.
- Rationale for the use of these practices and the effectiveness or efficiency of these practices.
- Issues to consider for determining risk management practices for nanoscale materials to include in the basic program.
- Comments on EPA's proposed risk management practices for nanoscale materials in the basic program.

EPA is also requesting comments on:

1. Other risk management practices for nanoscale materials that should be considered.

2. Consideration for possible additional risk management practices for nanoscale materials in the in-depth program.

IV. References

The following references have been placed in the public docket that was established under docket ID number EPA–HQ–OPPT–2004–0122 for this action as indicated under **ADDRESSES**.

1. NPPTAC. November 22, 2005. Overview of Issues for Consideration by NPPTAC.

2. Discussion paper for public meeting on risk management practices for nanoscale materials.

3. Agenda for public meeting on risk management practices for nanoscale materials.

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Nanoscale materials.

Dated: September 22, 2006.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. E6–16385 Filed 10–3–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2006–0785; FRL–8064–2]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Comments must be received on or before November 3, 2006. **ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0785, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2006–0785. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http:// www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going

Appendix B

MEETING AGENDA

United States
Environmental Protection Agency

Public Meeting on Risk Management Practices for Nanoscale Materials

L'Enfant Plaza Hotel
Washington, DC
October 19-20, 2006

Agenda

THURSDAY, OCTOBER 19, 2006

8:00AM Registration

8:30AM **Introductions and Opening Remarks**

- Welcome ..... *Nhan Nguyen, U.S. Environmental Protection Agency (EPA)*
- Opening Remarks and Voluntary Nanoscale Materials Stewardship Program (NMSP) Status ..... *Jim Willis, EPA*
- Panel Introductions and Meeting Overview ..... *Jan Connery, Eastern Research Group, Inc. (ERG)*
- National Pollution Prevention and Toxics Advisory Committee Recommendations and EPA Proposed Approach to Risk Management Practices in NMSP Basic Program ..... *Scott Prothero, EPA*

9:00AM **Panel Discussion: Proposed Approach and Elements for Risk Management Practices in NMSP Basic Program**

10:30AM BREAK

10:45AM **Panel Discussion: Personal Protective Equipment**

12:15PM LUNCH (on your own)

1:15PM **Panel Discussion: Engineering Controls**

2:45PM BREAK

3:00PM **Panel Discussion: Waste and Release Management (including spills)**

4:30PM **Day 1 Summary**

5:00PM ADJOURN

(over)

FRIDAY, OCTOBER 20, 2006

8:00AM	**Panel Discussion: Worker Training and Work Practices**
9:30AM	BREAK
9:45AM	**Panel Discussion: Hazard Communication/Product Labeling/Customer Training**
11:15AM	**Panel Discussion: Considerations for Risk Management Practices in the In-depth Program**
11:45AM	LUNCH
1:00PM	**Panel Discussion: Considerations for Risk Management Practices in the In-depth Program (continued)**
2:00PM	**Facilitator Summary**.....*Jan Connery, ERG* **EPA Closing Remarks**.....*Robert Lee, EPA*

Note: The last 15 minutes of each Panel Discussion is set aside for public comment (10 minutes) and facilitator summary (5 minutes) on the topic.

Appendix C

DISCUSSION PAPER

Discussion Paper for Public Meeting on Risk Management Practices for Nanoscale Materials

Meeting Background and Purpose

As part of EPA's initiatives to address growing interest in the potential health and safety issues of nanoscale materials (NMs), EPA is developing the voluntary Nanoscale Materials Stewardship Program (NMSP). This program is being designed to encourage responsible commercial development of NMs. The NMSP will also enable EPA, the affected industry, and interested stakeholders to enhance their ability to effectively and efficiently assess potential risks to human health and the environment from NMs and to identify risk management practices (RMPs) which may reduce such potential risks.

EPA has received input from the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) regarding the intended outcomes of a voluntary program. NPPTAC's overview document (NPPTAC 2005) includes a range of potential intended outcomes for a voluntary program, including:

1. Give EPA, and the public to the extent possible recognizing legitimate CBI issues, a better understanding of the types of nanoscale materials; the physical, chemical, hazard and exposure characteristics of such substances; the volume of such substances; and the uses of such substances;
2. Help EPA develop capacity and a process to identify and assess risks of nanoscale materials;
3. Help EPA determine what information it needs about nanoscale materials and articulate those information needs to industry and other stakeholder groups;
4. Help EPA understand what risk management practices are being used at production, processing, use and disposal stages, and what additional risk management practices need to be implemented;
5. Prompt or reinforce the implementation of risk management practices; and
6. Provide the information and experience needed to develop an overall approach to the treatment of nanoscale chemical substances under TSCA that builds public trust in nanoscale materials while enabling innovation and responsible development.

NPPTAC has indicated that participants in a voluntary program should agree to implement basic risk management practices (RMP) or other environmental or occupational health protection controls (e.g., worker training; hazard communication (including MSDS); use of available engineering controls; provision of personal protective equipment (PPE), product labeling, customer training, waste management practices, etc.).

As part of the development of the voluntary program, NPPTAC also suggested that EPA hold one or more public scientific peer consultation(s) to determine (1) what risk management practices should be included in a Basic Program[1] and (2) what additional risk management practices should be included in an In-depth Program[1].

EPA is holding this public scientific peer consultation as suggested by NPPTAC. For this meeting, EPA has developed this meeting discussion paper to outline key RMP information found in literature, to present proposed elements of RMP to be included in the Basic Program, and to present questions for consideration. EPA has also convened a peer panel to review the discussion paper and to comment on RMPs that should be included in the NMSP, to discuss additional information on RMPs for NMs, and to summarize input for EPA to consider for finalizing RMP to include in NMSP. The panel is to provide individual comments and is not to arrive at joint decisions, reach consensus, or provide majority advice.

Meeting Objectives

EPA has established the following specific objectives of the public meeting:

1. To inform the public and industry of EPA's level of understanding of the topics and considerations for RMPs for the NMSP;
2. To further develop EPA's and others' understanding of RMPs currently used for NMs, the rationale for the use of these practices, and the effectiveness or efficiency of these practices;
3. To discuss issues and to gain input on including RMPs for a NMSP Basic Program and an In-depth Program.

Discussion Overview

The remainder of this paper begins with a summary of a proposed approach to Risk Management Practices (RMPs) in NMSP.

The seven specific topic areas for RMPs noted by NPPTAC were slightly broadened (as noted in parentheses) and combined as follows for the purpose of this meeting.

1. Personal Protective Equipment
2. Engineering Controls
3. Waste Management (includes Environmental Release Management and Spills)
4. Worker Training (includes Work Practices)
5. Hazard Communication / Product Labeling / Customer Training

[1] NPPTAC indicates that EPA's voluntary program should offer participants the opportunity to participate in a basic program, or in a more in-depth program that includes all the elements of the basic program, as well as the commitment to generate and report more in-depth information, and implement more in-depth risk management practices.

Key information from a limited literature search is summarized for each topic area. "Approaches to Safe Nanotechnology - An Information Exchange with NIOSH" (NIOSH, 2006) is the primary source document for workplace-related issues. Proposed NMSP Basic Program Information/ Data Elements are listed after the Literature Information Summaries. Panel Discussion Questions are listed following the Proposed Elements, and these questions will guide the discussion of the Panel at the meeting.

Discussion Details

Proposed Approach and Elements for Risk Management Practices

Literature Review Key Information Summary

- The implementation of a risk management program in workplaces where exposure to nanomaterials exists can help to minimize the potential for exposure to nanoaerosols. Elements of such a program should include:
  - evaluating the hazard posed by the nanomaterial based on available physical and chemical property data and toxicology or health effects data.
  - assessing potential worker exposure to determine the degree of risk.
  - the education and training of workers in the proper handling of nanomaterials (e.g., good work practices).
  - the establishment of criteria and procedures for installing and evaluating engineering controls (e.g., exhaust, ventilation) at locations where exposure to nanoparticles might occur.
  - the development of procedures for determining the need and selection of personal protective equipment (e.g., clothing, gloves, respirators).
  - the systematic evaluation of exposures to ensure that control measures are working properly and that workers are being provided the appropriate personal protective equipment. (NIOSH 2006, p. viii)

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the Basic Program Element questions in each of the five topic areas/ groupings identified in bold lettering below.

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for RMP? If so, please include the information and cite reference(s).
2. Is the approach for RMP appropriate for the NMSP Basic Program? If not, please specify changes to the approach that should be considered.

1. Personal protective equipment (PPE)

a) Respirators

Literature Review Key Information Summary (all bullets below from NIOSH 2005, pp. 23-25)

- Respirators may be necessary when other controls do not keep an airborne contaminant below a regulatory limit or internal control target
- Decision on respirator should be based on a combination of professional judgment and results of hazard assessment and risk management practices
- Effectiveness of controls can be evaluated using measurement techniques described in Exposure Assessment and Characterization (section of NIOSH 2006)
- To assist respirator users, NIOSH has published the document NIOSH Respirator Selection Logic (see www.cdc.gov/niosh/docs/2005-100/default.html)
- Preliminary studies indicate that NIOSH certified respirators should provide the expected levels of protection if properly selected and fit tested (note: The most penetrating particle size range for a given respirator can vary based on the type of filter media employed and the condition of the respirator (For example, the most penetrating particle size for N95 respirators containing electrostatically charged filter media can range from 50-100 nm to 30-70 nm.)

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the following questions:

1. What worker activities may involve airborne particulates containing the NM?
2. What respiratory protection has been implemented for these activities?
3. What is the rationale for the selection of the respirator? For air-purifying respirators, do you have data on respirator cartridge efficacy?
4. Has an internal exposure control target been determined for this NM? If so, what are the target and the rationale for the target? Do you have data (e.g., personal sampling, etc.) to determine whether the target has been met, and if so, and what measurement techniques have been employed to detect the NM?

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).
2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

b) Personal protective clothing (e.g., gloves, etc.)

Literature Review Key Information Summary

- No guidelines on selection for the prevention of dermal exposure to nanoparticles are available (NIOSH 2006, p. 23)
- Penetration efficiencies for nanoparticles have not been studied (NIOSH 2005, pp. 22-23)
- Existing clothing standards already incorporate testing with nanometer-sized particles (e.g., ASTM F1671-03 for bloodborne pathogen penetration specifies use of a 27-nm bacteriophage) provide some indication of effectiveness of protective clothing with regard to nanoparticles (NIOSH 2006, p. 23)
- No NM-specific information for eye protection was found in the limited literature search.

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the following questions:

1. What worker activities may involve exposure to skin (dermal exposure) and to eyes to the NM or to mixtures containing the NM? What are the physical state(s) of the NM or mixtures containing the NM (for mixtures, include NM concentration)?
2. What skin or eye protection has been implemented for these activities?
3. What is the rationale for the selection of the protective clothing? For gloves, do you have data on efficacy toward NMs, and if so, what measurement techniques have been employed to detect the NM?

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).
2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

2. Engineering controls

Literature Review Key Information Summary

- For most processes and jobs, control of airborne exposure to nanoparticles can be accomplished using a wide variety of engineering control techniques similar to those used in reducing exposures to general aerosols (NIOSH 2006, p. 22)
- Current knowledge indicates that a well-designed exhaust ventilation system with a high-efficiency particulate air (HEPA) filter should effectively remove nanoparticles (NIOSH 2006, p. 22)

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the following questions:

1. What worker activities may involve airborne dust containing the NM?
2. What engineering controls have been implemented for these activities?
3. What is the rationale for the selection of the engineering control? For air-purifying filters, do you have data on filter efficacy, and if so, what measurement techniques have been employed to detect the NM? Do you have data (e.g., personal sampling, area monitoring, etc.) on efficacy of other controls, and if so, and what measurement techniques have been employed to detect the NM?

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).
2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

3. Waste and release management (including spills)

Literature Review Key Information Summary

- Follow any existing federal, state, and local regulations
- No specific guidance is available on cleaning up nanomaterial spills; consider potential for exposure during cleanup (e.g., re-aerosolization, etc.) (NIOSH 2006, pp. 25, 30)
- Collection of all NM waste materials for disposal in compliance with the site-specific Hazardous Waste Management Plan (Texas A&M, p. 6)

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the following questions:

1. What waste streams and other releases (include all day-to-day and emergency response wastes and releases to all media, including fugitive dust emissions; equipment cleaning; emptied transport containers such as bags or drums; used respirator cartridges, HEPA filers, or gloves; etc.) may contain the NM?
2. What release controls and waste management practices have been implemented for these wastes and other releases? Do you dispose of any wastes as hazardous wastes? Do you treat any waste or release streams containing NMs on your site?
3. What is the rationale for the selection of the controls or practices? Where applicable, do you have data to determine whether the controls or practices (on-site or off-site) are effective, and if so, what measurement techniques have been employed to detect the NM in airspace, water, or other environmental samples?

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).
2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

4. Worker training / Work practices

Literature Review Key Information Summary

- Hazard information on common materials that are being manufactured in the nanometer range (e.g., TiO 2) should be considered as a starting point in developing work practices (NIOSH 2006, p. 14)
- Incorporating good work practices in a risk management program helps minimize worker exposure to nanomaterials; examples include (NIOSH 2006, p. 22):
  - Cleaning work areas at the end of each work shift (at a minimum) using HEPA vacuum pickup and wet wiping methods. Dry sweeping or air hoses should not be used to clean work areas. Cleanup and disposal should be conducted in a manner that prevents worker contact with wastes and complies with all applicable Federal and State, and local regulations.
  - Preventing the storage and consumption of food or beverages in workplaces where nanomaterials are handled.
  - Providing hand-washing facilities and encouraging workers to use them before eating, smoking, or leaving the worksite.
  - Providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas (including take-home) caused by the transfer of nanoparticles on clothing and skin.
- Regular training on respirators, including OSHA guidelines for voluntary use of respirators [29 CFR 1910.34 Appendix D] (NIOSH 2006, p. 24)

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and provide information to EPA that is responsive to the following questions:

1. What worker training specific to the NM do you provide?
2. What are your work practices (include those mentioned above) for handling NMs at your site(s)?

Panel Discussion Questions

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).
2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

5. Hazard communication/ Product labeling/ Customer training

Literature Review Key Information Summary

- No NM-specific information for hazard communication (haz-comm), product labeling, or customer training was found in the limited literature search.
- There are many uncertainties as to whether the unique properties of nanomaterials (which underpin their commercial potential) also pose occupational health risks (NIOSH 2006, p. 6).
- Although insufficient information exists to predict the fire and explosion risk associated with nanoscale powders, nanoscale combustible material could present a higher risk than coarser material of similar quantity given its unique properties (NIOSH 2006, p. 12).
- Depending on their composition and structure, some nanomaterials may initiate catalytic reactions and increase their fire and explosion potential that would not otherwise be anticipated from their chemical composition alone (NIOSH 2006, p. 13).

Proposed NMSP Basic Program Elements

NMSP participants will be asked to consider the literature review information and to provide information to EPA that is responsive to the following questions:

1. What are your approaches to haz-comm, product labeling, and customer training for the NM?
2. What information do you provide in your MSDS for the NM?
3. What information specific to the NMs do you include on the product labels?
4. Do you institute any special customer training for NMs?

Panel Discussion Questions

1. Are there examples of haz-comm, product labeling, or customer training for NMs? If so, what aspects of these examples for NMs differ from similar examples for non-NMs?
2. Beyond the haz-comm, product labeling, and customer training traditionally practiced, are there other aspects of these topics that need to be considered or implemented for NMs?
3. Is key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

4. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

6. Considerations for RMP in the In-depth Program

Participation in the basic program would include a risk management component that consists of a participant's agreement to implement basic risk management practices or other environmental or occupational health protection controls (e.g., worker training; hazard communication (MSDS); use of available engineering controls; provision of personal protective equipment, product labeling, customer training, waste management practices, etc.). Participants should describe their experience in implementing, and their degree of satisfaction with, Basic Program risk management practices. (NPPTAC 2005, p. 5)

The In-Depth Program would be expected to focus on a more limited number of nanoscale materials, generating and reporting more in-depth information that would allow the Agency to conduct a more complete and detailed risk assessment of the identified materials and associated uses. The program would also need to have a focus on identifying representative nanomaterials for testing, risk mitigation technologies and related research. For each volunteered material, producers, processors, users, and researchers and/or consortia of such entities would submit Basic Program information and would concurrently begin to generate the additional, more in-depth information, although it is expected that it will take longer to generate the new information. In-depth information on the nanoscale materials could be developed on a set of key elements, developed by EPA in advance of program launch, including material characterization, human health hazard, environmental hazard, environmental fate, release and exposure, and exposure mitigation. The information would be generated with an aim to avoid redundancy and ensure efficient use of resources.

Under the In-Depth program, volunteers would also agree to work to extend application of protective risk management practices identified by EPA along their supply chains, and to conduct monitoring of workplaces, environmental releases and worker health. (NPPTAC 2005, p. 6)

Panel Discussion Questions

1. How might RMP elements be changed or expanded for the In-depth Program?

References

NIOSH 2006. National Institute for Occupational Safety and Health. July, 2006. Approaches to Safe Nanotechnology - An Information Exchange with NIOSH. http://www.cdc.gov/niosh/topics/nanotech/safenano/

NPPTAC 2005. National Pollution Prevention and Toxics Advisory Committee. November 22, 2005. Overview of Issues for Consideration by NPPTAC.

Texas A&M Engineering. "Interim Guideline for Working Safely with Nanotechnology." http://engineering.tamu.edu/safety/guidelines/Nanotechnology/NANO_SafeGuideline.pdf

Appendix D

PRELIMINARY PANEL COMMENTS ON DISCUSSION PAPER

Comment Compilation of Panelists' Preliminary Responses to Panel Discussion Questions Posed in the Discussion Paper for the Public Meeting on Risk Management Practices for Nanoscale Materials

A compilation of panelists' preliminary comments received in response to "Panel Discussion Questions" contained in the Discussion Paper for the Public Meeting on Risk Management Practices for Nanoscale Materials is provided below. Comments are organized by the following seven topic areas that correspond to the meeting sessions:

- General Observations;
- Risk Management Practices (RMP) in NMSP Basic Program;
- Personal Protective Equipment;
- Engineering Controls;
- Waste and Release Management (including spills);
- Worker Training and Work Practices;
- Hazard Communication/Product Labeling/Customer Training; and
- Considerations for RMP in the In-Depth Program.

General Observations

Dr. John Balbus – Environmental Defense:

"1) The discussion paper does a good job of combining the NPPTAC summary recommendations and the NIOSH information exchange paper as the reference sources for "key literature" review.

2) Both the NPPTAC summary and this document focus more or less exclusively on workplace risk management. While this is a critical initial focus, I would like to see the basic program include information on what risk management practices have been implemented or are being considered for consumer and environmental protection. These might include control of product disposal and other end of lifecycle issues, or special labeling for consumer use.

3) There is no description of what risk management practices might be included for implementation (in addition to reporting) under the basic program aside from a statement this would be part of the program on page 9. I'm assuming this is the first part of the agenda on Thursday. If not, this needs to be included, and some description in this paper would have been helpful.

4) Similar to the implementation part of the basic program, there is very little detail provided on the in-depth program, and thus very little to comment on. This part seems to have an hour at the end of the two days. This may not be sufficient time and attention to this part.

5) The specific questions and literature aspects for each of the 5 areas appear to be appropriate. Some additional resources are listed below.

There are several additional efforts in developing and sharing risk management practices for nanotechnology, of which the EPA should be aware. These include:

Environmental Defense-DuPont partnership

DuPont, a global science company, and Environmental Defense, an environmental non-profit organization, are working together to develop a framework for the responsible development, production, use and disposal of nano-scale materials. We are engaging a broad range of stakeholders for input and feedback as we develop a framework that is proactive, practical, and adaptable. The framework addresses environmental, health and safety risk management for nanotechnology products under the circumstances of limited ability to fully assess those risks. It is meant to allow users to revise decisions and practices in the face of new or additional information, data or concerns. It is intended to be relevant to a wide range of stakeholders, including companies, public interest groups, academia, standards developing organizations and government agencies. We anticipate releasing the first draft of the framework in the Spring of 2007.

ICON survey

ICON has contracted with UC Santa Barbara to survey current practices in handling of nanomaterials from a variety of settings around the world. This survey should be available within the next few weeks to months.

Texas A and M website

This website has compiled a variety of guidance documents on working with nanomaterials safely, including the NIOSH guidance.
http://engineering.tamu.edu/safety/new/templates/nanotechnology.html

Article in Chemical and Engineering News
This article is worth including in the literature reviewed for its summary of current efforts.
http://pubs.acs.org/cen/coverstory/84/8418nanotechnology.html

ASTM document

ASTM is currently balloting a guidance document on safe handling practices for nanomaterials. I don't know when this will be available for public use.

American National Standards Institute/ISO

The US is leading efforts on a New Work Item on a technical report for safe handling of nanomaterials. This is in very early stages."

Mr. James Cooper – Synthetic Organic Chemical Manufacturer's Association (SOCMA):

"The Agency may want to consider using a different term for Risk Management Practices, which results in the acronym "RMP," to avoid confusion with the Air Office's Risk Management Program (RMP). Industry EH&S professionals associate RMP with the Clean Air Act and are not going to be familiar with this new context. Several alternatives include:

- Risk Management Approaches (RMAs)
- Risk Management Methods (RMMs)
- Risk Management Strategies (RMSs).

SOCMA believes that expanding communications about why nanoscale materials should be managed differently than other particulates would benefit participants, especially smaller companies. Some sample language on how to communicate these concepts is as follows:

> In air, nanoscale materials may not behave in the same physical manner as larger particulates. Our current understanding is that nanoscale materials possess unique physical properties. It is reasonable to expect materials that are nanoscale in three dimensions, when released to air, may behave in a similar manner to aerosols or certain molecules in a gaseous or vapor phase. When selecting appropriate protective clothing and gloves, attention should be paid to the porosity of the protective material in addition to compatibility. For protective eyewear, it may be advisable to use vapor-proof goggles, versus traditional eyewear for particulates."

Mr. William Gulledge – American Chemistry Council (ACC):

"The [Nanotechnology Panel (Panel) of the American Chemistry Council] will be submitting additional written comments on RMPs following the public meeting.

The Panel appreciates the opportunity to participate in this public forum regarding a voluntary nanoscale materials stewardship program, believes such a program is critically important for the responsible development of nanotechnology and strongly supports efforts to collaborate with non-government organizations, academia, small and medium sized enterprises, and other key stakeholders to identify ways to achieve success that are effective and consistent with our member companies' commitment to Responsible Care®, product stewardship, and sustainability. Indeed, the Panel was formed in 2004 in large part to achieve these ends.

Specifically, the Panel was formed to foster the responsible development and application of nanotechnology, to coordinate nanotechnology environmental, health, and safety research initiatives undertaken by member companies and other organizations, and to facilitate the exchange of information among member companies and other domestic and international organizations on issues related to applications and products of nanotechnology. The Panel supports nanotechnology products and applications consistent with the Responsible Care® Program to ensure that the commercialization of nanoscale materials proceeds in a way that protects workers, the public, and the environment. In this regard, the Panel supports product

stewardship for nanomaterials and strongly supports the gathering of data to facilitate an effective nanomaterials risk management approach.

The Panel's commitment to the responsible development of nanotechnology is evidenced in many ways as discussed below and through its partnering with Environmental Defense (ED). Along with ED in 2005, the Panel issued a Joint Statement of Principles that reflects the parties' shared view of several core principles on which a comprehensive governmental program for addressing potential risks of nanoscale materials should be premised:

- Some applications of nanomaterials are expected to offer significant societal and sustainable development benefits.

- The timely and responsible development and regulation of nanomaterials in an open and transparent process will best assure that nanomaterials are being developed in a way that identifies and minimizes potential risks to human health and the environment.

- A multi-stakeholder dialogue that includes all interested parties, including small businesses, labor, community organizations, and consumer advocates, as well as large businesses and environmental organizations, will best assure the development of an effective program for nanoscale materials.

- A significant increase in government investment in research on the health and environmental implications of nanotechnology is essential.

- The development of an international effort to standardize testing protocols, hazard and exposure assessment approaches, and nomenclature and terminology is an important step to maximize resources and minimize inconsistent regulation of nanomaterials.

- Elements of safe and responsible development of nanotechnology should include appropriate protective measures while more is learned about potential human health or environmental hazards.

- A government program should address intentionally produced nanoscale materials produced in or imported into the U.S. and characterize hazard and exposure sufficiently to assess any risks of these materials. It should also assess the appropriateness of or need for modification of existing regulatory frameworks.

The Panel Urges the Development of Definitions and Terminology for Nanoscale Materials as an Appropriate First Step before Tackling Hazard/Risk Characterization/Management Issues

The Panel believes that the development of definitions and terminology for determining what is a nanomaterial for EPA and related government programs is a critically important first step in defining the universe of materials subject to evaluation in any risk assessment program. The

Panel believes that this issue should be addressed first, and if possible, a consensus reached as quickly as possible among the various entities evaluating nanotechnology and nanomaterials.

Furthermore, after appropriate definitions and terminology have been established, the Panel believes that EPA should focus on developing hazard assessment tools, methodologies, and protocols before seeking to conduct risk assessments and/or establishing subsequent risk management programs or practices. To evaluate potential consumer exposures, for example, it is essential to consider hazard data including available toxicology data from the nanoscale materials conventionally-sized counterparts, and identification of any unique properties associated with the nanoscale version of the same material. This review should be considered well before attempting to characterize or establish possible risk management practices.

The Panel urges EPA to schedule a future public meeting similar to the meeting that is the subject of this notice to focus on hazard identification and characterization issues. Indeed, the Panel believes that it might have been more appropriate to conduct such a meeting prior to the present meeting, but since that is not possible, a hazard assessment public forum should follow as soon as practicable.

The Panel Has Proactively Surveyed Current Work Practices and Intends to Share the Results at the October Meeting

At the forthcoming meeting on October 19-20, the Panel will summarize the results of a recently conducted work practices survey. This survey was conducted among Panel member companies. The initial results from this survey reveal that the participating Panel member companies employ appropriate and effective risk control measures in work environments where engineered nanoscale materials are used. The Panel intends to provide further information on this important subject, which is directly relevant to the scope of the review at the forthcoming meeting, and the Panel is aware of other efforts underway to the examine work practices of producers and users of nanomaterials.

In addition to reviewing the results of the Panel's recently completed work practices survey, the Panel is presently engaged in several other projects centered on the responsible development of nanotechnology. In brief, these projects include an update on the results of an industry consortium's (which include several Panel member companies) efforts to produce, replicate, and measure engineered nanoparticles in the workplace and to confirm the effectiveness of existing protective personal clothing and equipment to control exposure to these materials. This work is being supplemented by several National Institute for Occupational Safety and Health pilot studies presently underway, and by the ICON survey on workplace risk management practices."

<u>Dr. Jacqueline Isaacs – National Science Foundation (NSF) Center for High-rate Nanomanufacturing (CHN):</u> No general comments.

<u>Dr. Kristen Kulinowski – International Council on Nanotechnology (ICON) and Center for Biological & Environmental Nanotechnology Rice University:</u>

“ICON provides information on nanomaterial environmental, health and safety
The International Council on Nanotechnology (ICON) is an international, multi-stakeholder organization whose mission is to develop and communicate information regarding potential environmental and health risks of nanotechnology thereby fostering risk reduction while maximizing societal benefit. The council has evolved into a network of scholars, industrialists, government officials and public interest advocates who share information and perspectives on a broad range of issues at the intersection of nanotechnology and environment, health and safety. We maintain a public portal for information on nanomaterial environmental health and safety (EHS) at http://icon.rice.edu.

ICON members are committed to identifying and closing knowledge gaps that hinder the development of responsible practices for managing the potential risks of nanomaterials to workers, consumers and the environment. Pursuant to that goal ICON published the first free database of citations to peer-reviewed scientific publications on nanomaterial EHS and maintains this database as a public service. With over 1600 references, the nano EHS database is routinely accessed by people from around the world. In addition, ICON is working to develop an international assessment of research needs for nanomaterial EHS that is flexible, adaptive, prioritized and reflective of the multistakeholder spirit that underlies all of our activities. The first of two workshops to develop the research needs assessment will be held at the National Institutes of Health facility in Bethesda, MD on January 9-10, 2007.

ICON documents current practices in nanomaterial handling in the workplace
Most relevant to today's public meeting is the ICON project to document current practices for identifying, managing and reducing risks for the production, handling, use and disposal of nanomaterials. The current practices survey is intended to help companies manage potential nanotechnology risks with more certainty. Our goal is to identify the safest way to work with nanomaterials by first identifying the approaches in use today by industries that are already developing and using nanomaterials. ICON also hopes the initiative will help inform risk management efforts that are underway at the National Institute for Occupational Safety and Health, the Environmental Protection Agency and other federal agencies.

In March 2006, ICON commissioned researchers at the University of California—Santa Barbara to perform a comprehensive survey of industry practices for handling nanomaterials. Work on the project was completed in two phases. The Phase 1 report, Current Knowledge and Practices regarding Environmental Health and Safety in the Nanotechnology Workplace, publicly released on October 18, 2006, offers a comprehensive review of all existing “best practice” development efforts. The findings of this report highlight an existing gap that the Phase 2 report seeks to fill. Namely, the Phase 1 report finds that existing efforts to catalogue workplace practices have not systematically documented current EHS practices in a variety of workplace settings and geographies. Moreover some of the existing documents are not publicly available. The Phase 2 effort was directed at plugging these gaps by surveying a broad range of companies internationally to determine current practices. One of the major goals of the final report is to identify critical needs for the standardization and implementation of safe practices in the nanotechnology industry worldwide so that current practices can evolve into globally adopted best practices.

The survey was administered between June and September 2006 to sixty-four companies, research labs, and university labs on four continents through telephone interviews and written and web-based surveys. The questionnaire inquired about current practices related to Occupational Health and Safety Program, Engineering Controls, Personal Protective Equipment and Clothing (PPE), Waste Management of Nanomaterials, Monitoring the Work Environment for Nanoparticles, Perception of Risk of Nanomaterials Handled, Methods for Determining Risk of Nanomaterials, Toxicity Testing, and Product Stewardship. The scope of the survey makes it directly responsive to this panel's scope and, therefore, we anticipate that it will provide valuable information to EPA as it considers the development of risk management practices. The final report is currently in draft form and will be released via a teleconference on November 13, 2006.

Environmental Defense and DuPont Risk Framework

Since September 1, 2005, DuPont, a global science company, and Environmental Defense, an environmental non-profit organization, have been working together to develop a framework for the responsible development, production, use and disposal of nano-scale materials. According to Environmental Defense and DuPont, the intent of their framework is to define a systematic and disciplined process that can be used to identify, manage and reduce potential health, safety and environmental risks of engineered nanomaterials across all lifecycle stages. In their attempt to develop a framework that will be used and accepted by a wide range of stakeholders, DuPont and Environmental Defense have been sharing elements of their framework with a wide range of audiences, including ICON and EPA, since May 2006. They plan to pilot-test this framework on specific nano-scale materials or applications and release a detailed draft of the framework early next year.

Voluntary consensus processes for developing RMPs

In January 2005 ASTM International, one of the world's largest voluntary standard development organizations, created the E56 Committee on Nanotechnology to develop globally adopted standards for nanotechnology in such areas as terminology, metrology and environment, health and safety. The group is in the advanced stages of editing document ASTM E56-03 WK8985 Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings, which lays out guidelines for workplace practices that are directly relevant to the scope of this meeting. The document is currently being reviewed and a new standard may be available before the end of the year. WK8985 is meant to provide general guidance on handling nanomaterials in the absence of relevant exposure standards or definitive risk and exposure information. The emphasis is on minimizing exposure to unbound engineered nanomaterials through use of engineering controls, administrative work practices and personal protective equipment. The guide is comprehensive in scope, covering hazard assessment and evaluation, exposure assessment and exposure risk evaluation, exposure minimization methods appropriate for a variety of occupational settings and circumstances, response to accidental or unanticipated releases of unbound engineered nanomaterials, and hazard communication. It is anticipated that, when finalized, WK8985 will be the first formal standard for occupational risk minimization of nanomaterials.

The American National Standards Organization and ISO are also engaging in voluntary standards development. In June 2005, in response to the formation of ISO/TC 229 Nanotechnologies, the American National Standards Institute (ANSI) formed the ANSI-

Accredited U.S. Technical Advisory Group (TAG) to ISO/TC 229 Nanotechnologies. Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office serves as Chair of this U.S. TAG and acts as the Head of Delegation to the ISO/TC 229 Meetings. ANSI serves as TAG Administrator as well as Secretary to ISO/TC 229 WG 3 Health, Safety and Environment. This ANSI-accredited U.S. TAG is open to all materially-effected U.S. interested parties, and currently has over 55 members from various sectors of Industry, Government, Academia, Standards Developing Organizations and NGOs. The structure of this U.S. TAG mirrors the structure of ISO/TC 229, with three TAG Working Groups in Terminology and nomenclature; Measurement and characterization and Health Safety and Environment. These TAG Working Groups act as advisory bodies to the full U.S. TAG, recommending U.S. positions on draft standards, technical reports and questionnaires, as well as developing proposals for review and approval by the full U.S. TAG.

The International Organization for Standardization (ISO) approved the establishment of a new Technical Committee on nanotechnology, ISO/TC 229 Nanotechnologies in June, 2005. 27 national bodies hold Participating membership on ISO/TC 229 while 8 national bodies have Observer status. There are three Working Groups currently operating under ISO/TC 229:

- Working Group (WG) 1 - Terminology and Nomenclature – Leadership assigned to Canada
- Working Group (WG) 2 - Measurement and Characterization – Leadership assigned to Japan
- Working Group (WG) 3 - Health, Safety and Environment – Leadership assigned to United States

Mr. Steven Brown of Intel Corporation is the Convener of the U.S.-led Health, Safety and Environment Working Group. ISO/TC 229 WG 3 is currently developing a Technical Report "Current safe practices in occupational settings relevant to nanotechnologies," which was submitted to ISO/TC 229 by the United States. Dr. Vladimir Murashov is the Project Leader on the development of this ISO Technical Report. ISO/TC 229 held their inaugural meeting in November 2005, in London, United Kingdom. A second ISO/TC 229 meeting was held in June, 2006 in Tokyo, Japan. ISO/TC 229 will meet again in December, 2006 in Seoul, South Korea."

Dr. Andrew Maynard – Woodrow Wilson International Center for Scholars:

"This discussion paper sets out elements of a Risk Management Program (RMP) for engineered nanomaterials, to be implemented by participants in a voluntary Nanoscale Materials Stewardship Program (NMSP). The overall structure of the RMP follows good occupational hygiene practices. However, the challenge is in adapting these practices to the potentially unique risks presented by some engineered nanomaterials. The proposed RMP is a good start. But in places it reflects a superficial understanding of good workplace risk management practices, and does not fully embrace current accepted philosophies, such as taking hierarchical approach to exposure control. It is also relatively weak in providing direction and guidance on how the size-dependent behavior of engineered nanomaterials should be addressed in a RMP.

The proposed RMP draws heavily on information from NIOSH – an agency with over thirty years experience of protecting workers through research and recommendations. Given NIOSH's reputation, experience, expertise and mission, it would seem reasonable to expect the agency to play a leadership role, rather than a secondary role, in developing the elements of a RMP for engineered nanomaterials.

Finally, the draft document offers little in the way of support for developing robust RMP in the face of considerable uncertainty over how to assess and manage possible risk. Working within this uncertainty will require the development and application of alternative risk management approaches, such as Control Banding. But it will also require research into effective risk management methods.

In summary, this draft document is a good starting point for developing a robust approach to managing the risk of engineered nanomaterials in the workplace. With further input from industrial hygienists, leadership from NIOSH and additional information on how to apply the elements to nano-specific issues, it will form a valuable component of the NMSP."

Additional Resources

Maynard, A. D. & Kuempel, E. D. (2005) Airborne nanostructured particles and occupational health. Journal Of Nanoparticle Research 7, 587-614.

DEFRA (2006). UK Voluntary Reporting Scheme for engineered nanoscale materials. London, UK. Department of Environment, Transport and the Regions.

ICON EHS database. icon.rice.edu/research.cfm.

Project on Emerging Nanotechnologies Inventory of current Nanotechnology Environment, Safety and Health Research. www.nanotechproject.org/18

Maynard, A. D. (2006). Nanotechnology: A research strategy for addressing risk. Washington DC. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

Nanotechnology Consensus Work Place Safety Guidelines. ORC Worldwide. http://www.orc-dc.com/Nano.Guidelines.Matrix.htm

Dr. Valdimir Murashov and Dr. Charles Geraci – National Institute for Occupational Safety and Health (NIOSH):

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of the Stewardship Program.

To improve this document further, the following general comments can be made.

NIOSH is conducting strategic, multidisciplinary research on the occupational health and safety applications and implications of nanotechnology. This research will help scientists and policymakers to 1) determine if nanomaterials pose a risk for work-related health and safety effects, 2) design prudent measures for working with nanomaterials pending greater insight into health and safety questions, and 3) apply the unique properties of nanomaterials to innovations for preventing occupational injuries and illnesses.

NIOSH regularly reviews available information on nanotechnology risk assessment and risk management and regularly updates dynamic guidelines including those on nanomaterials handling which are posted at http://www.cdc.gov/niosh/topics/nanotech/.

In light of rapidly evolving nature of nanotechnology and our knowledge base about its occupational safety and health, it could be suggested that participants of the program are referred to NIOSH Approaches to Safe Nanotechnology for most recent guidelines on nanomaterials handling in occupational setting (http://www.cdc.gov/niosh/topics/nanotech/safenano/).

In addition, the participants of the Stewardship program should be encouraged to

1) periodically review documents posted on NIOSH nanotechnology web-site as this web-site and most of the documents posted on it are regularly reviewed to maintain their content current;
2) partner with NIOSH Nanotechnology Field Team in assessing exposures and effectiveness of control technologies to reduce exposures to nanomaterials.

In developing Risk Management Practices for Nanoscale Materials as part of the Stewardship Program, the following documents developed recently should be considered:

1. Draft NIOSH Current Intelligence Bulletin: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide (available at http://www.cdc.gov/niosh/review/peer/Tio2/).

2. UK Voluntary Reporting Scheme for engineered nanoscale materials (available at http://www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-nanoscale.pdf);

3. Laboratory Management, Draft Health and Safety guidelines for Nanotechnology Research at the National Laboratories, University of California (available at http://labs.ucop.edu/internet/ES&H/draft_hs_guidelines.html);

4. NIOSH Nanoparticle Information Library (http://www.cdc.gov/niosh/topics/nanotech/NIL.html).;

5. Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials. 2006. NSET report available at http://www.nano.gov/NNI_EHS_research_needs.pdf.

In addition, EPA should be aware of the following activities related to Risk Management practices in occupational setting documents currently in progress:

1. International Council on Nanotechnology (ICON) funded a survey of Current Practices for Nanomaterial Handling. The report summarizing results of the survey is expected to be released later this year (http://icon.rice.edu/projects.cfm?doc_id=4388).

2. International Organization for Standardization (ISO) Technical Committee 229 Nanotechnologies, Working Group 3 (Health, Safety and Environment) is developing a Technical Report on "Current safe practices in occupational settings relevant to nanotechnologies". It will act as an informational foundation for identifying areas suitable for development of standards.

3. Organization for Economic Cooperation and Development's Working Party on Manufactured Nanomaterials under the Chemicals Committee in the Environmental Directorate is developing program of work to focusing on implications of manufactured nanomaterials."

Mr. Sean Murdock - NanoBusiness Alliance:

"The NanoBusiness Alliance and its EHS Leadership Council look forward to the October 19-20, 2006 to address risk management practices (RMP) as part of a possible voluntary stewardship program for engineered nanoscale materials. This document sets forth initial responses to the questions posed in the discussion document, but the NanoBusiness Alliance EHS Leadership Council will be submitting more comprehensive comments on RMPs following the public meeting.

The NanoBusiness Alliance commends EPA's efforts to move the voluntary nanoscale materials stewardship program (NMSP) forward. We believe the NMSP will play an important role in the responsible development of nanotechnology, by accelerating the development of knowledge on nanomaterials while safeguarding workers and the public. The NanoBusiness Alliance and its membership has demonstrated an interest in and a willingness to work with Congress and the agencies to ensure the nation sees the benefit of its investment in nanoscience: Over 50 nanotechnology executives have flown to Washington, DC to give annual briefings to Congressional staff and to engage the agencies and regulatory bodies, including EPA and NIOSH. Furthermore, NanoBusiness Alliance members have been at the forefront in cooperating with NIOSH in its site visits and efforts to understand current workplace environments.

As EPA proceeds with the development of the NMSP, it is critical that we establish clear terminology and nomenclature. Nanomaterials are absolutely not monolithic and treating them as monolithic is not helpful. The development of terminology and nomenclature is critical not only for scoping the voluntary program, but also for ensuring effective risk management practices and risk communication.

In addition to rapidly getting clarity around terminology and nomenclature, it is critical that EPA develop hazard assessment tools, methodologies, and protocols before seeking to conduct risk assessments and/or establishing subsequent risk management programs or practices such as would be the case with the in-depth program. Without standards that define how a given material should be prepared for testing, what test and methods should be used and how the

findings should be reported, we will not be able to reach an meaningful assessment of the hazard of the specific nanomaterial, without which it is not possible to determine acceptable exposure levels or to accurately inform risk management practices. The NanoBusiness Alliance recommends that EPA schedule an additional public meeting to focus upon hazard identification and characterization issues to discuss these challenges in the near future.

In addition to the NIOSH document referred to in the discussion questions, the NanoBusiness Alliance is aware of several bodies of work that EPA should leverage as it develops the RMP guidelines for the NMSP:

a) Nanoparticle Occupational Safety and Health (NOSH) consortium is working toward: the development of a method to generate a well-characterized aerosol of solid nanoparticles and to measure aerosol behavior as a function of time; the development of an air sampling method that can be used on a day-to-day basis in laboratories and manufacturing settings; and the ability to measure barrier efficiency of filter media with respect to specific engineered aerosol nanoparticles

b) ICON and UCSB have just completed a detailed analysis of current environmental, health and safety (EHS) and product stewardship practices in sixty-four companies, research labs, and university labs on four continents. The questionnaire inquired about current practices related to research, use and manufacture of nanomaterials (< 100 nm size) in the following areas: environmental health and safety training, use of engineering controls, personal protective equipment and clothing (PPE) recommendations, exposure monitoring, waste disposal, product stewardship practices, and risk characterization.

c) ASTM has a standard in development for “Handling Unbound Engineered Nanoparticles in Occupational Settings”

d) Texas A&M has produced an “Interim Guideline for Working Safely with Nanotechnology”

Because we recognized that the above studies may not be complete and available for this meeting, the NanoBusiness Alliance conducted a brief survey of the later stage nanotechnology companies who either have commercial revenues or are moving toward commercial production to develop a basic and qualitative understanding of the risk management practices in place. The initial results from this survey suggest that member companies employ appropriate and effective risk control measures in work environments where engineered nanoscale materials are used.

The following is the NanoBusiness Alliance’s response to questions posed by the EPA public hearing on Risk Management Practices (RMPs) for Nanoscale Materials (NMs). The response is intended to help inform the EPA effort to develop a voluntary Nanoscale Materials Stewardship Program (NMSP) and is informed by a survey of NanoBusiness Alliance member companies with regards to their Personal Protective Equipment (PPE) practices, engineering controls, waste and release management strategies, worker education and training initiatives and their hazard communication and customer training policies. Having said that, the diversity of companies,

materials, and manufacturing methods involved makes answering any of these questions in an aggregated format difficult to impossible. We expect that the NMSP itself will enable answers to be developed for the more detailed and targeted questions as the program begins to collect this data on a material specific basis, so have kept responses to a higher level.

Definition of Terms

A common response to the discussion paper circulated by the EPA has been that it uses several terms without providing clear definitions. The paper does not include a clear definition, for example, of the term "nanotechnology" or of terms such as "nanoaerosol" or "nanomaterial." Without standardized definitions for these terms, it is not possible for stakeholders in the debate to interpret them consistently. Several members pointed out that in the case of the term "nanomaterial," the subject area is so broad and the various materials are sufficiently different in terms of their properties and behaviors that a separate discussion should be taking place for each material. Since hazard varies from material to material, this fundamentally impacts the question of tolerable exposure and the RMPs that need to be employed.

Mr. Ronald White - Johns Hopkins Bloomberg School of Public Health: No general comments.

Proposed Approach and Elements for Risk Management Practices in NMSP Basic Program

1. Is additional key information available that is not included in the literature summary for RMP? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"SOCMA believes that EPA has done an adequate job reviewing the public literature and agrees with its conclusions. SOCMA conducted cursory literature reviews and found that nano-specific information is somewhat lacking. Like EPA, SOCMA found that traditional standards organizations have already begun work studying nanoscale materials and that results are only beginning to be published. Most work to date has been in the area of nomenclature and physical measurement. SOCMA is not aware of any additional studies or publications addressing the specific aspects of risk management practices for nanoscale materials. There are general references, however, for handling fine particulates in publications by the National Fire Protection Association (NFPA), NIOSH, OSHA, AIGCH and others traditionally involved in risk and emergency management. These could serve as interim resources until more definitive information is available."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"Maynard and Kuempel (2005) consider the following elements:

- The propensity of a nanomaterial to release inhalable and respirable particles into the air during manufacturing, handling or cleanup.
- Attributes of released airborne particles such as small diameters, nanostructure, high surface area, unique surface chemistry and other size and structure related properties that may lead to differences in hazard when compared to that for the component chemicals.
- Attributes of released aerosol particles that indicate the use of exposure metrics other than mass-based metrics.
- Whether relationships between different exposure metrics such as specific surface area will enable the extension of conventional mass based exposure monitoring approaches to airborne engineered nanomaterials.
- Appropriate measures that can be taken to characterize and reduce or eliminate exposure."

Dr. Murashov and Dr. Geraci:

"In view of uncertainties regarding the potential for hazard of specific engineered nanoscale materials and great variability of chemical composition and structure of nanomaterials, it has been proposed that tiered-based risk management approaches, such as control banding or risk management toolkit, that do not rely on traditional exposure-limit-based approaches could be employed for ensuring safety and health in the workplace and of the environment (Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, 2006. NSET report is available at http://www.nano.gov/NNI_EHS_research_needs.pdf.). It could be instructive to request additional information as follows:

a) Is control banding approach to managing risks employed?
b) Is tiered approach used in assessing and managing risks of nanomaterials? If yes, what are the details of this approach (such as nanomaterials binning)?"

Mr. Murdock: Specific comments were not provided.

Mr. White:

"The first bullet item under "Worker Training/Work Practices" key information regarding use of existing hazard information on common nanomaterials as a starting point for risk management practices and controls has applicability to the entire scope of the Basic and In-Depth RMP programs and should be included under this section."

2. Is the approach for RMP appropriate for the NMSP Basic Program? If not, please specify changes to the approach that should be considered.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"The program elements that the Agency has outlined appear to be appropriate. The language and tone of some of the questions, however, may need some adjustment. Much of the language in the elements contains terminology used in the field of industrial hygiene and may not be familiar to EH&S professionals outside of the industrial hygiene realm. Additionally, the tone of the questions concerning rationale, possession of data and measurement techniques may appear intimidating to those who do not regularly deal with EPA."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"The term "nanoaerosols" is not defined in this document. It needs to be clear whether this refers to free nanometer-scale particles in the air, airborne particles with an exposed nanostructure, or airborne particles with a nanostructure which is not directly accessible. The RMP should address all engineered nanomaterials where exposure might potentially occur – including powders, suspensions and slurries, as well as aerosols."

Dr. Murashov and Dr. Geraci:

"In general the approach appears to be sound. It could be recommended to stress that at this stage risk assessment and risk management of nanotechnology is a dynamic process rapidly evolving as we obtain new data."

Mr. Murdock: Specific comments were not provided.

Mr. White:

"The description of the RMP approach for the NMSP Programs (pg. 3) should not be limited only to a focus on nanoaerosols, though exposure to aerosolized nanomaterials is appropriately a primary focus of the risk management program. As noted in the 2004 Royal Society and the 2006 NIOSH reports, nanomaterial manufacture often involves a liquid phase that can be a source of potential risks from exposures through dermal contact with slurries/suspensions/solutions that contain nanomaterials. Consideration of potential dermal exposures to nonaerosolized nanomaterials should be addressed in the RMP approach for the NMSP protocol.

Consistent with the recommendation included in the 2004 Royal Society/Royal Academy of Engineering report as well as the 2005 NAPTAC meeting report, it should be explicitly stated that health and environmental hazard data and exposure information, and the methodologies used to obtain them, that are generated through the Basic and In-Depth Programs will be made available in the public domain, consistent with the confidential business information provisions under TSCA Section 14. Confidential business information claims for data and information developed under these programs should be carefully evaluated by EPA to ensure they meet CBI thresholds."

Personal Protective Equipment

a) Respirators

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"SOCMA suggests asking for the information in a similar flow to a pre-manufacture notice (PMN). The participant could begin with a discussion of how the material is processed, where potential releases may occur, a description of worker activities that could lead to exposure, including the potential route of exposure, and controls and PPE used to protect workers. Then have a section that asks participants to describe how the product is used (if known), how the material may be released during use, activities that could lead to exposures, and recommendations to users on protective measures. It would also be appropriate to include information about how equipment is cleaned, disposal of empty containers and product residue, and if and how waste streams are treated. This would avoid redundant questions and appear less like an interrogation and more like a reporting format."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs:

"The only information I know of is the two studies funded by NIOSH – data presented at the Minneapolis meeting but not yet published. The last bullet on p. 4 references some of these data.

Key information:

1. Worker activities – in our experience, any activity that involves manual handling of nanoscale particles (NSPs) or involves mechanical energy being applied to them (e.g., adding NSPs to an extruder). For example, concentrations from 25,000 – 50,000 particles/cm^3 during extruder experiments were observed which is very high.

2. Respirator protection – we haven't developed our rules yet – that will be part of our best practices. However, exposures as high as that above should require respirator use. Workers in our cleanroom (where typically dry NSPs are not used) requires all workers to wear face masks which provide adequate protection for our activities. Handling exposed dry NSPs should always require the use of respirators.

3. We have not collected data on respirator performance, but based on the preliminary data presented by NIOSH at the Minneapolis meeting, N100 cartridges (HEPA cartridges) should be highly efficient while N95 (cheaper, less efficient filters) cartridges appear to let some NSPs through. Based on this, workers exposed to NSPs should take the precautionary approach & use N100 cartridges. A well-fitted half-mask facepiece should be sufficient (i.e., full-facepiece or air-supplied respirators not necessary)."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"Consideration of respirator use must occur within a hierarchical risk management program. This must first establish that exposure cannot be reduced to acceptable levels without the use of respirators. To make this judgment, exposure control targets must first be established, exposure monitored and engineering control solutions implemented.

A key component of the RMP will be identifying activities and processes that lead to the generation of airborne nanostructured materials – not just activities that involve airborne particulates containing nanomaterials."

Dr. Murashov and Dr. Geraci: Specific comments were not provided.

Mr. Murdock: Specific comments were not provided.

Mr. White:

"Reference to the OSHA respiratory protection standard and voluntary guidelines should be added to the literature summary for this topic."

2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: See above comments.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: "Appears appropriate."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: See above comments.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of basic program."

Mr. Murdock: Specific comments were not provided.

Mr. White:

"The program element should specifically ask whether respirator use under Question #2 is mandatory or voluntary in addition to the rationale for the type and level of respiratory protection selected for those workers identified as potentially having contact with NM containing particulates."

b) Personal Protective Clothing

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: See above comments under respirators.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs:

"See question 1 above for respirators – same thing holds for clothing. In addition, NSPs in liquids may present a challenge to clothing if exposures occur. If proper protection is used

similar to that used in dealing with acids when handling liquids, that could be sufficient. Our class 10 cleanroom garment includes latex gloves and Tyvek® suits offers adequate protection for our researchers.

Our best practices will probably recommend latex or nitrile gloves, Tyvek® suits, and goggles for anyone potentially exposed to NSPs via skin or eyes. Our limited data on gloves suggests that latex & nitrile work will but cotton does not – this is probably true for any other woven material, such as shirts etc – leading to the recommendation for Tyvek®."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: Specific comments were not provided.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of basic program."

Mr. Murdock:

The following are practices we suggest be incorporated as part of the basic voluntary program:

- Providing appropriate personal protective equipment (PPE) where engineering controls are not feasible or where exposure is likely even with those controls in place.

Mr. White:

"Reference to the fact that human factors are likely to play a significant role in the level of effectiveness of SPEs against dermal exposure to nanomaterials should be added (Texas A&M 2005, Schneider 1999)."

2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: See above comments under respirators.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: "The question on efficiency data should be expanded to include protective clothing."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: "This seems to be an appropriate set of elements."

Mr. Murdock: Specific comments were not provided.

Dr. Murashov and Dr. Geraci: See comments above.

Mr. White: "The elements of this topic are appropriate for the NMSP Basic Program."

Engineering Controls

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

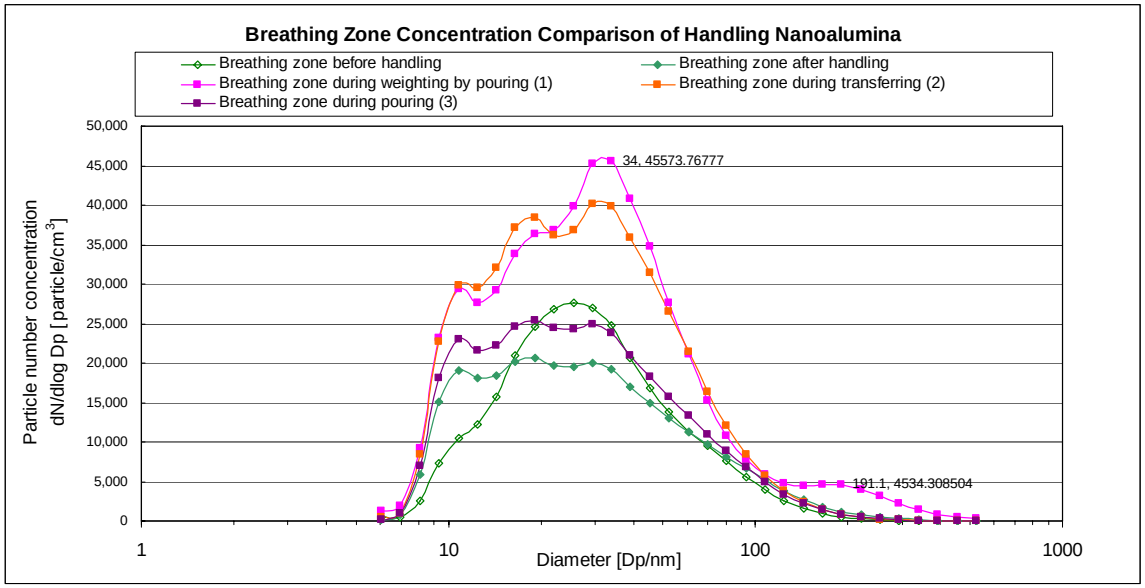
Dr. Balbus: Specific comments were not provided.

Mr. Cooper: See above comments under PPE.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs:

"Just unpublished data. We are using local exhaust ventilation (LEV) to control exposures – e.g. – fume hoods, LEV on extruders. NSPs in NSPs transport and deposition in clean environments have been looked down to 100 nm for the last two decades. Smaller particles however, have not received as much attention. We have no data on filters – will collect this year. For LEV effectiveness, we have recent work doing NSP powder transfer in a fume hood. The results are still very preliminary but they show that a laboratory fume hood can be effective, but that it can also be problematic if not used properly.



The important curves are labeled 1 (magenta) and 3 (dark purple?). In each case alumina powder (nanoscale size) is transferred by spatula from one beaker to another, as you might do if one is weighing it. The measurements were taken outside the hood, near her breathing zone. Note that curve 3 is essentially equal to the background concentration measured before & after the experiment (green curves), while curve 1 shows a significantly elevated concentration of 30 nm particles (the size of the nanoalumina). The only difference between the conditions is that for curve 1 the hood sash was wide open (bad) and for curve 3 it was half-open (good), improving both the physical isolation and the air velocity. So the message is that fume hoods have to be evaluated to quantify their performance, then they have to be operated properly in order to be effective."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: Specific comments were not provided.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of basic program."

Mr. Murdock:

The following are practices we suggest be incorporated as part of the basic voluntary program:

- Enclosure or isolation of processes that generate nanoparticles, particularly aerosols (for example, glove boxes or other forms of engineering controls) where feasible
- Local exhaust ventilation that will prevent nanoparticles entering the employee's breathing zone (hoods, wet benches, etc.)
- Review of the toxicology of the base materials being used.

Mr. White:

"It should be noted that the control effectiveness of engineering controls is highly dependant on appropriate use and maintenance of engineering control systems (Texas A&M Engineering, 2005)."

2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: Specific comments were not provided.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs:

"The second bullet should be expanded to include other particle control devices beyond HEPA filters, such as fabric filters and electrostatic precipitators. Large-scale industrial processes will not want to use HEPA filters, because they are expensive and non-cleanable. However, in normal clean environment (such as cleanrooms) a typical HEPA filter is expected to last for 15-20 years of continuous operation."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"The first element in this section should consider activities and processes that lead to the release of or exposure to airborne engineered nanomaterials, rather than activities that involve airborne dust containing nanomaterials.

In the third element, it is necessary to know the standard to which filters have been evaluated, the relevance of this standard to the aerosol being produced, whether non-standard evaluations have been conducted (and the results), and whether in-situ tests of efficacy (including the filter housing) have been conducted."

Dr. Murashov and Dr. Geraci: See comments above.

Mr. Murdock: Specific comments were not provided.

Mr. White:

"A program element should be added regarding how appropriate use and maintenance of engineering control systems are addressed."

Waste and Release Management (including spills)

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: See above comments under PPE.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: Specific comments were not provided.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of basic program."

Mr. Murdock:

The following are practices we suggest be incorporated as part of the basic voluntary program:

- Review maintenance/post-processing activities and develop a spill / disposal strategy.

Mr. White:

"Reference to the fact that energetic cleaning methods (e.g. sweeping, compressed air) should be avoided or used only in conjunction with HEPA filtration should be added (NIOSH 2006)."

2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Mr. Gulledge: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"The one element I would consider as missing here is what criteria are used to determine acceptable levels of engineered nanomaterial release. The default position may be zero emissions or release, but this is likely to be impractical, and only able to be implemented at the detection limit of the monitoring instrumentation used."

Dr. Murashov and Dr. Geraci: See comments above.

Mr. Murdock: Specific comments were not provided.

Mr. White: "The elements of this topic are appropriate for the NMSP Basic Program."

Worker Training and Work Practices

1. Is additional key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"The key information summary provides a good foundation for standard procedures when handling nanoscale materials. "

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs:

"We do (at CHN) regular H&S training for students/faculty – basically training them to avoid all exposures – respiratory & skin."

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: No additional comments at this time.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended risk management practices for occupational setting and puts forward questions which will provide valuable information if they are implemented as part of basic program."

Mr. Murdock:

The following are practices we suggest be incorporated as part of the basic voluntary program:

- Education and training for all employees whose job responsibilities bring them in contact with nanomaterials (chemists, engineers, techs, hazardous materials/waste handlers, contractors handling these materials, etc.)
- Development of appropriate standard operating procedures that include safe handling procedures for nano-related processes and activities.
- Conducting periodic industrial hygiene monitoring of work areas where nanomaterials are generated, used or otherwise handled. This may be in the form of air sampling or wipe sampling; qualitative assessments should also be considered.

Mr. White: No additional key information.

2. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"Question 2 of the proposed elements may need to be more explicit. It is difficult to determine what the Agency is looking for, regarding "work practices." Similar questions on worker activities were asked in previous sections. If EPA is look for hygiene practices, then perhaps the question should ask:

> Describe personal and other hygiene practices for handling NMs at your facility. Please include hygiene practices for cleaning work areas, disposal of material, personal hygiene and disposition of protective clothing."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: No additional comments at this time.

Dr. Murashov and Dr. Geraci: See comments above.

Mr. Murdock: Specific comments were not provided.

Mr. White: "The elements of this topic are appropriate for the NMSP Basic Program."

Hazard Communication/Product Labeling/Customer Training

1. Are there examples of haz-comm, product labeling, or customer training for NMs? If so, what aspects of these examples for NMs differ from similar examples for non-NMs?

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"Hazard communications for very fine particulates have been around for some time. MSDSs and other forms of communication usually provide cautionary statements and methods to avoid dust generation, don appropriate protective gear, disposal techniques, known hazards, etc. One thing that may be missing, however, is a statement on the uncertainties associated with the physical properties and potential hazards of nanoscale materials. This information could be standardized and placed on the MSDS or take the form of a separate sheet as an addendum.

The proposed elements for HazComm seem to be a little vague. It may be advisable to ask the participant what type of additional information they provide that is unique to their nanoscale materials. MSDS information will often follow the ANSI format, so asking Question 2 the way it is written will probably result in a listing of the MSDS sections."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: "To my knowledge, nothing is available beyond the NIOSH (2006) document."

Dr. Murashov and Dr. Geraci:

"Web-based search revealed that hazard communication materials range from "hazard effects are unknown, treat with care"-type statement to using hazard information for bulk materials of the same chemical composition, to using hazard information for other forms of materials with the same elemental composition. This is a reflection of the lack of standards including nomenclature standards and paucity of hazard data when it comes to nanomaterials."

Mr. Murdock: Specific comments were not provided.

Mr. White:

"I am not aware of any examples of haz-comm, product labeling or customer training specifically for nanomaterials."

2. Beyond the haz-comm, product labeling, and customer training traditionally practiced, are there other aspects of these topics that need to be considered or implemented for NMs?

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"Another idea for training and communication could be to produce a video that generally describes what is known about NMs and the uncertainties regarding physical/chemical properties and hazards. The video could be produced and distributed through a variety of sources, such as OSHA, NIOSH, NFPA, EPA, etc. Perhaps an ad hoc multi-stakeholder group could be formed to conceive and produce the video, the MSDS addendum and other educational materials."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"Producers, handlers and users of engineered nanomaterials need to be aware of potential nano-specific behavior which might lead to unanticipated hazards. These include the discussed catalytic behavior and combustion potential. But they also include hazards associated with mixing different nanomaterials, high dispersion potential in low density materials, surface contamination from spills and physical and chemical structure-dependent toxicity."

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended hazard communication products for nanomaterials."

Mr. Murdock:

The following are practices we suggest be incorporated as part of the basic voluntary program:

- Review current literature addressing EHS issues re nanomaterials (toxicology, sampling methodologies, PPE recommendations, environmental impact, etc.) and react appropriately to significant changes or approaches
- Provide relevant and meaningful information and data in Material Data Sheets for synthesized materials.

Mr. White:

"Assuming appropriate toxicity and hazard risk potential information are available, approaches to haz-comm, product labeling and customer training for nanomaterials can be consistent with that for other chemicals or substances with potential health concerns. However, the current and anticipated near-term lack of toxicity and hazard risk data for most nanomaterials suggests that a more precautionary and generalized approach will need to be applied to the content of haz-comm, product labeling and customer training compared to traditional practices for chemicals."

3. Is key information available that is not included in the literature summary for this topic? If so, please include the information and cite reference(s).

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: Specific comments were not provided.

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: Specific comments were not provided.

Dr. Murashov and Dr. Geraci:

"This discussion paper presents a good summary of recommended hazard communication products for nanomaterials."

Mr. Murdock: Specific comments were not provided.

Mr. White: No additional key information

4. Are the elements for this topic appropriate for the NMSP Basic Program? If not, please specify changes to the proposed elements and their bases.

Dr. Balbus: Specific comments were not provided.

Mr. Cooper: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Mr. Gulledge: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard: "These elements seem to be a reasonable starting point"

Dr. Murashov and Dr. Geraci:

"Given the paucity of hazard information about nanomaterials, it could be recommended including the following question: "what is the basis for using these MSDSs?" It will provide valuable information if implemented as part of the basic program."

Mr. Murdock: Specific comments were not provided.

Mr. White: "The elements of this topic are appropriate for the NMSP Basic Program."

Considerations for RMP in the In-Depth Program

1. How might RMP elements be changed or expanded for the In-depth Program?

Dr. Balbus: Specific comments were not provided.

Mr. Cooper:

"The elements of the in-depth program should be developed by a multi-stakeholder group and not solely by EPA. To achieve buy-in for the program, it will be important to continue the stakeholder input that began with the NPPTAC. A task force could be established, including multiple agencies, industry, environmental and public health groups, and others. Although the size of the group should be limited, SOCMA believes that a stakeholder approach is essential to the ultimate success of the program."

Mr. Gulledge: Specific comments were not provided.

Dr. Isaacs: Specific comments were not provided.

Dr. Kulinowski: Specific comments were not provided.

Dr. Maynard:

"I would consider risk management practices sufficiently important that the best possible practices are followed in all workplaces producing or using engineered nanomaterials. I would therefore argue against implementing different standards of RMP in the basic and in-depth programs.

However, in the context of the in-depth program, research and collaborations to fill critical information gaps and develop more robust RMP frameworks should be considered. Maynard (2006) for instance addresses short-term critical research questions relevant to working safely with nanomaterials, and considers mechanisms for providing answers within an acceptable timeframe. As well as the need for an adequately funded top-down strategic risk-focused research framework within government, the report recommends developing mechanisms for joint government-industry funded research."

Dr. Murashov and Dr. Geraci:

"This discussion paper presents an outline of the In-depth Program with details to be developed. The outline suggests that the In-depth Program can yield important information which could be further utilized in conducting risk assessment and risk management of nanomaterials."

Mr. Murdock: Specific comments were not provided.

Mr. White:

"A time frame for implementation of the elements of the In-Depth Program relating to extension of RMPs to supply chains, and monitoring of workplaces, releases and worker health should be included in the In-Depth Program concept description so companies can consider these factors in their decision-making on whether to join the In-Depth Program."