Meeting Summary Report
Nanoscale Materials Stewardship Program

(August 2, 2007 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 remarks and public comments made during the public meeting on the voluntary Nanoscale Materials Stewardship Program (NMSP) organized by the U.S. Environmental Protection Agency (EPA). The meeting was announced in a Federal Register notice (72 FR 38081, 12 July 2007) and took place in Arlington, Va. on August 2, 2007 at the Holiday Inn Rosslyn at Key Bridge.

The meeting agenda was structured to allow formal comments from eight, pre-registered stakeholders. Time in the afternoon was also allocated to allow additional stakeholders who requested time to speak to make public comments. An opportunity to make any additional comments or ask questions was provided. The meeting concluded with a question and answer session focusing on key issues that were specifically identified by EPA in the Federal Register notice. Appendix A contains a copy of the meeting agenda.

The meeting brought together 124 participants, including stakeholders in academia, non-governmental organizations (NGOs), government, industry, professional organizations, the press, international entities, and the general public. Appendix B presents the final list of observers.

Eastern Research Group, Inc. (ERG), a contractor to EPA, provided logistical support and prepared this summary report. 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. Formal, written comments that are received per instructions in the Federal Register notice will be incorporated into the public docket.

1.1 Background and Purpose

In two separate Federal Register notices, EPA announced the availability of the "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" and the "TSCA Inventory Status of Nanoscale Substances - General Approach" (72 FR 38083, 12 July 2007) and the proposed Information Collection Request's supporting statement and draft reporting form (72 FR 38079, 12 July 2007). The purpose of the meeting was to discuss and receive comments on the development of the voluntary NMSP, including comments on the associated program documents referenced above.

1.2 Key Questions

EPA outlined several key questions for stakeholders' consideration. These questions were intended to form the basis of discussion for this meeting. EPA specifically asked for input from participants on each question after conclusion of the comment presentations. The discussion is summarized in Section 3.0 of this document. Specifically, EPA (through the FR notice) asked stakeholders to comment on:

1. Whether the data elements that have been identified in the NMSP are appropriate for nanoscale materials;

2. The timing and phasing of submissions under the NMSP basic and in-depth programs and whether approaches for tiering data submissions are appropriate;

3. Who would participate in the NMSP and how to encourage participation, especially from small and medium sized enterprises;

4. What criteria to use for NMSP program evaluation and views on the timing and nature of any reports the Agency may issue;

5. How to engage industry and other stakeholders in the NMSP in-depth program and approaches for generating test data;

6. The processes and roles for EPA, participants, and other stakeholders during development and evaluation of data for the in-depth program;

7. Possible approaches for identification and use of alternative sources of data, in order to minimize the burden of information collection associated with the NMSP;

8. Uses for the data submitted to EPA under the NMSP program;

9. Issues relevant to scope, definitions and descriptions;

10. The suitability of the approach for determining the TSCA Inventory status of nanoscale materials discussed in the Inventory paper; and

11. Whether, in combination, the TSCA Inventory paper and the NMSP concept paper are sufficiently clear in how EPA plans at this time to address nanoscale materials that are new or existing chemicals under TSCA and the NMSP.

2.0 REMARKS AND COMMENTS

2.1 Introductory Remarks

Jim Willis (Director, Chemical Control Division, Office of Pollution Prevention and Toxics, EPA) greeted meeting participants and provided an overview of logistics for the meeting. He also reminded participants that comments must be submitted to the Docket by September 10, 2007.

Jim Gulliford (Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, EPA) provided keynote remarks. Mr. Gulliford thanked participants in advance for their input and noted that stakeholder input is an integral piece of the process for developing a voluntary program. Mr. Guilliford acknowledged that the use of nanoscale materials is an exciting field with many potential benefits, but recognized that, as a new technology, the proper regulatory oversight is required to ensure responsible and safe development of nanoscale chemicals and applications under the Toxic Substances Control Act or TSCA.

Mr. Guilliford commented that EPA is working with other federal agencies engaged in research, development, and regulation to ensure adequate oversight of nanoscale materials. Mr. Gulliford emphasized that the Nanoscale Materials Stewardship Program is not a regulatory program or framework – it is a tool to inform EPA's overall approach to address nanoscale materials.

Charlie Auer (Director, Office of Pollution Prevention and Toxics, EPA) discussed the purpose of the meeting and provided a brief overview of the NMSP. Mr. Auer reiterated that the NMSP is one component of an overall approach for EPA to address nanoscale materials. Further, he stated that EPA has taken several actions over the last several years to address the oversight of nanoscale materials, including:

- Holding an initial meeting in June 2005 on the Toxic Substances Control Act (TSCA) and Nanotechnology.

- Working with the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), which produced an Overview Document for EPA's consideration in November 2005. The NPPTAC Overview Document identified issues related to development of a stewardship program for nanoscale materials under TSCA, and EPA has drawn from many of the NPPTAC concepts presented in the document.

- In October 2006, EPA launched a collaborative process to design a Nanoscale Materials Stewardship Program under TSCA to complement and support its efforts on new and existing chemical nanoscale materials. As part of this process, EPA developed draft documents pertaining to the design of the NMSP which were published in the Federal Register on July 12, 2007, including:

    - A Concept Paper for the Nanoscale Materials Stewardship Program,

- TSCA Inventory Status of Nanoscale Materials - General Approach, and

- An Information Collection Request for the NMSP that included a proposed optional reporting form.

Mr. Auer then provided an overview of each of these documents.

After completing the document summary, Mr. Auer then explained that EPA anticipates three phases for the NMSP. Phase 1 is the design phase and is ongoing. The second phase is the implementation stage where data on nanoscale materials would be gathered by participants and submitted to EPA. The final phase is the evaluation phase, where EPA will assess progress, review any additional information collected to inform the evaluation, and determine the future direction of the program.

Mr. Auer stated that EPA intends to develop the details of the NMSP based on input from this public meeting, written public comments in response to the Federal Register Notices, input from the public scientific peer consultation on risk management practices for nanoscale materials held in October 2006, and the upcoming public scientific peer consultation on material characterization for nanoscale materials, which will be held September 6-7, 2007.

Mr. Auer encouraged industry and other stakeholders to actively contribute to the design and implementation of the NMSP. He noted that the understandings developed under the NMSP and the existing regulatory frameworks within which EPA must work will together inform EPA of the most appropriate next steps.

Mr. Auer reminded participants that EPA will be sponsoring a conference on pollution prevention through nanotechnology. The conference will be held on September 25-26, 2007. A primary purpose of the P2 conference is to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials. A second area of concentration is to identify and promote stewardship opportunities associated with applications of nanotechnology

2.2 Public Comments from Registered Speakers

Jim Willis initiated the public comment period by inviting registered speakers to present their comments, which was then followed by questions of clarification from the audience. Mr. Willis encouraged speakers to formally submit their statements as written comments to the Docket.

2.2.1 Dr. Shaun Clancy of Degussa Corporation on behalf of the American Chemistry Council

Dr. Clancy presented comments on behalf of the Nanotechnology Panel of the American Chemistry Council (ACC). Specific points made include:

- The Nanotechnology Panel believes that EPA has done a commendable job in developing the NMSP given the diversity of viewpoints;

- The Nanotechnology Panel supports the basic elements of the NMSP and the inclusion of both a basic and in-depth program, and believes doing so is an excellent way to encourage participation by those who may have limited data and/or information and/or may not have the resources needed to support development of new data;

- EPA and others should recognize that the use of nanomaterials may not be as widespread as some may have suggested;

- The Nanotechnology Panel urged EPA and others to measure the success of the program in terms of the value of the information submitted and its utility in assisting EPA in developing a firmer foundation for scientific, regulatory, and policy decision-making;

- Dr. Clancy noted that the Nanotechnology Panel has surveyed its members regarding their respective risk management practices and will make the results available to EPA and the public on the Panel's Web site (http://www.amercianchemistrycouncil.com/nanotechnology).

- The Nanotechnology Panel believes that it is important to manufacturers of nanoscale materials that confidential business information (CBI) remain confidential, and EPA's ability to protect CBI will enhance the likelihood of participation in the NMSP;

- The Nanotechnology Panel urged EPA that the NMSP recognize the importance of the need to characterize nanoscale materials;

- The Nanotechnology Panel questioned whether the NMSP would be able to determine the volume of nanoscale materials currently in use;

- The Nanotechnology Panel encouraged the submission of data under the MNSP for materials that are not explicitly included in the NMSP but may be thought to be nanoscale materials as it may provide a better, more reliable indication of the volumes of materials in commerce that are thought to be nanoscale, but actually may not be nanoscale;

- The Nanotechnology Panel noted that the NMSP does not address timing for submitting and reviewing information;

- The Nanotechnology Panel urged EPA to consider allowing participants of the basic program to submit data and information for a period of nine months after the NMSP formally begins;

- The Nanotechnology Panel urged EPA to consider allowing participants of the in-depth program to submit data and information for a period of two years after the

NMSP formally begins, but also allow the timeframe to be flexible given uncertainties; and

- Lastly, the Nanotechnology Panel urged EPA to consider identifying a target date to conduct an interim evaluation of the NMSP and a date for final evaluation of the NMSP.

EPA asked why the Panel recommended nine months for the basic program. Dr. Clancy explained that the Panel sought a need to impose a deadline to speed the program along.

2.2.2 Dr. Richard Denison, Environmental Defense

Dr. Denison presented comments on behalf of Environmental Defense. Specific points made include:

- Environmental Defense initially supported the proposal for a voluntary program under the premises that EPA would expeditiously enact a program that would quickly inform EPA and the public as to which nanoscale materials were in or soon to enter commerce and the extent of risk-relevant information that was available;

- Environmental Defense was disappointed that EPA is only now presenting the concept for the voluntary program, and was concerned that EPA has excluded key elements from the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) recommendations, specifically the lack of deadlines and no regulatory backstop;

- Environmental Defense concluded that it was unable to support EPA's proposal for a voluntary basic program given the delay, absence of deadlines, and absence of a regulatory backstop;

- Environmental Defense mentioned similar programs in the United Kingdom (UK) and Denmark and noted their poor rates of participation due to (in the opinion of Environmental Defense) the lack of such key elements;

- Environmental Defense noted that the Organization for Economic Cooperation and Development (OECD) has recently discussed how governments can make it easier for companies to participate in voluntary programs;

- Environmental Defense expressed concern over potential measures to increase participation discussed at the OECD, including: greater allowances for CBI claims, limiting the ways in which governments would use information submitted, and allowing data to be submitted in any form and format;

- Environmental Defense feels that the U.S. and other OECD members are losing sight of a key objective – to build public trust and confidence by making robust information available;

- Environmental Defense was concerned that there is significant potential for participation in a voluntary program to be both limited and selective which may result in a highly skewed picture regarding the range of nanoscale materials in or soon to be in commerce;

- Environmental Defense urged EPA to rapidly develop and implement mandatory reporting rules;

- Environmental Defense believes that mandatory reporting rules are the only viable means to ensure a level playing field and submission of a comprehensive and representative set of information;

- If EPA chooses to proceed with the voluntary program, Environmental Defense suggests that data be submitted under the basic program within three months while concurrently pursuing the use of reporting rules;

- With respect to the in-depth program, Environmental Defense observed that EPA's proposal does not address how its proposal relates to the OECD's Working Party of Manufactured Nanomaterials (WPMN) efforts to undertake in-depth hazard data development for representative nanoscale materials;

- Environmental Defense noted that EPA's resources and efforts would be better spent in ensuring that the WPMN initiative is as robust and executed as expeditiously as possible. Environmental Defense also stated that this work should focus on monitoring, estimating exposures, and personal protective equipment for nanoscale materials and urged working with NIOSH in this area immediately;

- Environmental Defense disagreed with EPA's proposed approach to determining the TSCA Inventory status of a nanoscale material;

- Environmental Defense believes that EPA's approach does not need to be based on precedent (i.e., EPA could use particle size to distinguish among substances on the Inventory even though it has not done so in the past).

- Environmental Defense also believes the approach reflects bad policy because it suggests that nanoscale materials are nothing new; thereby, eliminating any possibility of pre-market review through the New Chemical's Program;

- Environmental Defense highlighted their concerns regarding the use of Significant New Use Rules (SNURs) and noted that EPA will have serious challenges to overcome if EPA proposes the use of existing chemical SNURs as a means to ensure that engineered nanoscale materials are effectively assessed prior to commercial introduction; and

- Environmental Defense concluded that EPA's documents fail to acknowledge and consider the implications of the proposed approach with respect to EPA's ability both to carry out its responsibility to ensure that engineered nanoscale materials

do not pose undue risk to human health or the environment, and to keep up with the ever-accelerating pace of technology and new materials development.

2.2.3 Bernard Made, Environment Canada

Mr. Made provided an overview of Canada's perspective. Specific points made include:

- The NMSP needs to be properly framed in term of risk assessment and risk management;
- The NMSP needs to be considered within existing legal and regulatory contexts;
- Mr. Made explained that Canada has analogous programs that establish information requirements, and Canada maintains a Domestics Substances List that is very similar to the TSCA Inventory;
- Mr. Made noted that Canada would like to address nanomaterials as new chemicals based on properties that result in new effects;
- He indicated however that based on existing Canadian law some nanomaterials would be considered new and others would be considered existing, and that the distinction would be based on chemical structure;
- Canada encourages companies to contact regulatory authorities for assistance in making the determination;
- Environment Canada will be holding a meeting on September 27, 2007 in Toronto to discuss similar issues, and plans to release a proposed approach and discussion paper;
- Environment Canada published an advisory that explained two proposed phases of a program similar to the NMSP:
  - Phase 1 would describe regulatory issues and implications and would consist of an information gathering initiative to identify who, what, how much, how used, what is in commerce, and whether existing data exist. Mr. Made noted that it would be important to establish a baseline to inform future decisions and recognize if issues currently exist.
  - Phase 2 is expected to occur in mid-2008 and will address nomenclature issues, develop specific requirements, and consider significant new activity provisions of the Act for existing chemicals that will require additional data to be submitted.
- As part of a standard 5 year review, Canada's Parliament is considering modifying the Canadian Environmental Protection Act (CEPA);

- This is a parliamentary review so, it is unclear whether or not parliamentarians will consider changes to CEPA to establish special provisions for nanomaterials;

- Lastly, Mr. Made stressed the importance of international cooperation:
  - Agencies can benefit from international cooperation,
  - Environment Canada hopes that a similar approach between the U.S. and Canada can be developed,
  - Mr. Made mentioned that Canada is also involved with the OECD working group and the International Organization for Standardization, and
  - Environment Canada looks forward to information sharing.

Several questions of clarification were posed:

- Mr. Made confirmed that the legal framework within which Canada is working is similar to the U.S. and that Environment Canada will consider the appropriateness of characterizing nanomaterials as new chemicals in the future."

- Mr. Made confirmed that the information gathering effort will begin in 2008. Whether the effort will be voluntary versus mandatory has not been determined and will be a subject of the September meeting. He noted that a combined approach could be an option where some data are mandatory while other data could be voluntarily submitted.

- Mr. Auer thanked Mr. Made for Environment Canada's comments and reiterated that EPA is continuing to work very closely with Environment Canada and Health Canada.

2.2.4 Carolyn Nunley Cairns, Consumers Union

Ms. Cairns presented comments on behalf of Consumers Union. Specific points made include:

- EPA should ensure materials are safe prior to introducing them into commerce;

- A voluntary program is not sufficient given the potential risks;

- If a voluntary program is undertaken, EPA should ensure that a thorough substantiation of the submitted information occurs;

- Public access to information is critical;

- EPA must actively manage nanomaterials as new chemicals or as existing chemicals with significant new uses;

- Consumers Union is concerned that past lessons-learned are not being considered (e.g., Ms. Cairns alluded to past history regarding the uses of lead and mercury) – she argued that scientific understanding should precede consumer exposure to ensure that unidentified risks do not surface in the future. Ms. Cairns urged EPA to deal with nanotechnology differently to better anticipate risk and manage risks prior to entry into commerce;

- Consumers Union noted that the primary shortcomings of EPA's proposal are its voluntary nature and the potential for inadequate participation;

- Consumers Union commented that, given the current proposal, it was difficult to see how the NMSP could expedite EPA's and the public's understanding of nanomaterials;

- Consumers Union urged EPA to conduct mandatory pre-market assessments that, at a minimum, are conducted in parallel with the NMSP to ensure that consumers are not subjected to materials prior to EPA assessing risks;

- Consumers Union expressed concern over the lack of a reporting schedule;

- Consumers Union stressed the importance of ensuring publicly available information in a standardized format;

- Consumers Union suggested a two-track program whereby EPA could quickly get a sense of the current state while planning for detailed information requirements;

- Ms. Cairns noted that a recent investigation shows a wide-range of public opinions regarding risks and safety exists;

- Consumers Union reiterated that lack of evidence of harm is not an assurance of safety;

- Consumers Union is concerned that EPA appears to be ignoring the science that indicates nanomaterials are different enough that they should be considered new chemicals and EPA should also issue SNURs; and

- Consumers Union urged EPA to accelerate the regulatory process.

EPA reminded participants to read the information contained in the annexes of the documents. EPA requested that stakeholders comment on certain aspects that are presented in the annexes and specify whether content should be more prominently presented.

EPA indicated that it will consider Environmental Defense's position as comments and will consider them as the program is finalized. EPA noted that the proposed basic program was to span two years; however, the American Chemistry Council suggests nine months and Environmental Defense suggests three months followed by evaluation. EPA may consider a compromise between both suggestions if it is possible to accommodate a shorter duration. EPA

noted that the basic program has to be completed prior to moving forward and the quicker the better.

2.2.5 Scott Slaughter, the Center for Regulatory Effectiveness

Scott Slaughter presented comments on behalf of the Center for Regulatory Effectiveness. Specific points made include:

- Mr. Slaughter encouraged voluntary submission of data, and encouraged EPA to make the data publicly available when possible;
- Mr. Slaughter stressed that data must meet data quality standards in order to allow EPA to use the data, and he questioned how the data would be reviewed and be determined to be in compliance with quality requirements for use of data;
- Mr. Slaughter encouraged EPA to establish a system for screening data for compliance and require submitters to initially self-screen;
- The Center for Regulatory Effectiveness is concerned that the Office of Management and Budget will not approve the ICR without addressing such issues;
- Mr. Slaughter questioned whether the upcoming peer consultation on materials characterization would address data quality. [Mr. Auer responded to this inquiry by noting that EPA wants any data regardless of whether it is "scrubbed." He described EPA's standard method for assessing data quality and indicated the same process would be utilized for the NMSP. This process is based on the approach used when assessing new chemicals which requires that all information be submitted, some of which meets good laboratory practice (GLP) standards and OECD test guidelines. EPA assesses the quality of information submitted and may require further GLP testing if necessary.]
- After listening to Mr. Auer's response to his question, Mr. Slaughter suggested that EPA provide a similar explanation, within the context of data submitted for nanomaterials, in the supporting statement of the ICR;

2.2.6 Terry Davies, Woodrow Wilson Center

Terry Davies presented comments on behalf of the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars. Specific points made include:

- Mr. Davies reminded meeting participants of the latest report issued by the center: "EPA and Nanotechnology: Oversight for the 21st Century" that was published in May [available at: http://www.wilsoncenter.org/nano];
- Mr. Davies agreed that the NMSP is potentially useful and that it makes sense to have a program to inform the current state of nanotechnology so long as it does

not delay putting an adequate oversight system in place;

- Mr. Davies urged EPA to feel a sense of urgency to get a handle on the current state of these materials, as it is estimated that nanomaterials are introduced in products at a rate of five products/week;

- Mr. Davies was disappointed in the delay of initiating the NMSP and encouraged EPA to "just do it and quickly" regarding establishment of deadlines for implementing the program, receiving submissions, and ultimately ending the voluntary program;

- Mr. Davies raised concerns over his expected level of participation in the NMSP and noted that incentives are lacking;

- Mr. Davies is concerned about the definition of "chemical substance" presented in the TSCA Inventory paper. He stated that in his view, the Agency is binding itself to the current definition, and that rather than recognizing the issues associated with the definition, EPA should consider whether changes are warranted;

- Mr. Davies commented that the proposed policy ignores the important distinction that size makes a difference;

- Mr. Davies outlined several steps that he believes EPA should take, including:

  - Initiate a regulatory program in tandem with the NMSP to gain a double benefit of not delaying regulatory oversight and encouraging participation,

  - EPA should consider the past success of the 33-50 program and consider using it as a model,

  - EPA should recognize that the keystone to the regulatory effort should be a SNUR applied to all nanomaterials,

  - EPA should consider utilizing TSCA 8(a) as a supplement or potential substitute for a SNUR(s), and

  - The Inventory Paper needs to be revised to reflect that nanomaterials are not the same, in terms of biological or ecological characteristics, as the same material in the macroscopic scale.

2.2.7 James Cooper, Synthetic Organic Chemical Manufacturers Association

James Cooper presented comments on behalf of the Synthetic Organic Chemical Manufacturers Association (SOCMA). Specific points made include:

- Mr. Cooper explained that SOCMA's position is that fine particulates are not new chemicals, and that very few chemistries exist at the nanoscale;

- SOCMA noted that few products contain ingredients that are at the nanoscale;

- SOCMA also commented that no universal consensus on toxicity of nanomaterials as a whole exists and SOCMA recognizes that the unique properties warrant further research and consideration;

- SOCMA commented that many materials are currently being studied and the NMSP will facilitate quicker access to available information (noting that journals do not typically publish negative studies but the NMSP will gather this information);

- Mr. Cooper noted that he was a member of the NPPTAC sub committee. He stated that within the NPPTAC there was no consensus regarding development of a regulatory component, except as a regulatory backstop, but there was agreement that something would be helpful – exactly what was unclear;

- Mr. Cooper noted that there was some agreement within NPPTAC that if both a voluntary and regulatory program were run in parallel that would be a disincentive for a voluntary program and small companies may only focus on the regulatory requirements rather than participate in a voluntary program;

- SOCMA mentioned the High Production Volume Challenge Program and commented that EPA should review lessons-learned when implementing it. For example, EPA should recognize the importance of flexibility in timing (i.e., recognize that issues can arise with testing that must be overcome, that developing consortia takes time);

- SOCMA commented that the measure of the success of the program should be the number of substances sponsored not the number of companies.

- SOCMA reiterated the importance of handling CBI, noted that protection of CBI is critical to ensure success and adequate participation, and that CBI is the only way a small company has a competitive advantage particularly for new uses;

- SOCMA agreed that the data elements presented by EPA are sufficient

- SOCMA encouraged tiered participation whereby smaller firms would be less intimidated.

- SOCMA commented that the TSCA Inventory is a molecular-based list and that changing the basis for the Inventory would require significant review and modification of nomenclature issues;

- SOCMA encouraged stakeholders to give the NMSP a chance to work before instituting regulations;

- SOCMA noted that public recognition of NMSP participation is a very important incentive;

- SOCMA was supportive of EPA's suggestion to hold workshops to educate smaller entities about TSCA and the NMSP which is also an incentive to participation;

- SOCMA emphasized the importance of coordination with other federal agencies and the international community, especially with OECD;

- SOCMA commented that a key item related to information collection and the subsequent evaluation would be to focus on information that will allow trends assessment and facilitate predications based on these trends;

- SOCMA questioned the need for a broad SNUR if the NMSP is effective and suggested promulgating tailored SNURs, when necessary; and

- Lastly, SOCMA commented that if a regulatory component is developed, EPA should ensure that a level playing field exists among potentially affected entities.

2.2.8 Igor Linkov, Intertox, Inc.

Igor Linkov, Intertox, Inc. gave a presentation titled, "Multi-Criteria Decision Analysis and Nanomaterials Risk Management." EPA suggested that Mr. Linkov consider submitting the presentation to the Docket as comments, and Mr. Linkov indicated he would do so.

Mr. Linkov's presentation conveyed three primary points:

1. The relation of pattern, structure-activity and physico-chemical properties of nanoparticles on toxicity and life-cycle risk is widely unknown and available information is fragmented.

2. EPA View: Challenges of risk assessment and management for situations with a limited knowledge base and high uncertainty and variability require coupling traditional risk assessment with multi-criteria decision analysis (MCDA) and Adaptive Management to support regulatory decision making.

3. Industry View: Entities engaged in nanotechnology must consider practical and innovative steps to minimize identified risks while managing proactively for unknowns. EPA's stewardship program should provide value to business by helping focus on decreasing life-cycle product risk while keeping costs down.

Mr. Linkov encouraged EPA to be very explicit and clear on what information is needed and why. He also stated that EPA should covey how the information can be beneficial to industry. Mr. Linkov presented a case study that demonstrated how such information could be used to inform waste management decisions.

2.2.9 Kristin Kulinowski, International Council on Nanotechnology, Rice University

Dr. Kulinowski presented comments on behalf of the International Council on Nanotechnology (ICON). Specific points made include:

- Dr. Kulinowski indicated that ICON had engaged in considerable discussion regarding merits of the NMSP; however, ICON is not taking an formal position on the proposed program;
- Dr. Kulinowski indicated that ICON is united in efforts to develop a better understanding of interactions among nanomaterials and environmental health and safety;
- Specifically, ICON encouraged EPA to take action to:
  - Develop a publicly-accessible database of information gathered (e.g., physical/chemical data, and data on biological and environmental interactions) to facilitate advancement of basic knowledge,
  - Make as much effort as practical to present the data in the public domain, recognizing the importance of protecting CBI,
  - Structure data collection requests to conform to data standards and published consensus standards (e.g., ASTM, ISO) and encourage participants to use common submission formats, and
  - Continue to gather data on as many nanomaterials as possible.
- Dr. Kulinowski's stated that ICON's comments should not be interpreted as support for rigorous regulations;
- ICON is currently working to develop a needs assessment to evaluate what is known and the corresponding environmental and health and safety implications; and to direct resources toward gaps to facilitate obtaining information to better predict biological and environmental interactions. The goal of the project is the design of benign nanoscale materials and safe applications and the project is relevant to the data elements in the NMSP;
- ICON is developing a framework that will enable prediction of the interactions of nanomaterials;
- The summaries of two workshops that were held on these topics will be released in the fall. These summaries will highlight what characteristics were viewed as important by participants; and

- ICON looks forward to participating in the upcoming peer consultation on materials characterization.

2.2.10 Sean Murdock, NanoBusiness Alliance

Sean Murdock presented comments on behalf of NanoBusiness Alliance. Specific points made include:

- Mr. Murdock noted that the NanoBusiness Alliance has been a long-time supporter of the concept of the NMSP and commended EPA on the overall program design;

- NanoBusiness Alliance noted that it is critical that the NMSP create minimal burden on small companies, and that since the basic program does not require an organization to generate new data, it will encourage participation by small companies who have launched products;

- NanoBusiness Alliance cautioned EPA that recent media coverage may overestimate the market penetration and use of nanomaterials. NanoBusiness Alliance stated only a select few companies in the NanoBusiness Alliance are actually producing nanomaterials at the commercial scale;

- The NanoBusiness Alliance stated that the number of small companies is less than the ICR estimates because most companies are at the product development stage;

- The NanoBusiness Alliance believes that robust characterization of nanomaterials is fundamental to the success of the in-depth program;

- The NanoBusiness Alliance supports the principle of transparency and encourages companies to place information in the public domain when practical; and

- NanoBusiness Alliance stressed the importance of protecting CBI due to Intellectual Property considerations.

Several questions of clarification were posed:

- The concept of "intended for commercial use" was discussed. A participant questioned how many concept products have actually launched versus those that are in concept development. Mr. Murdock indicated that it is difficult to know for certain, but that many more products are in the concept development phase. He suggested that efforts should be focused on products that actually launch.

- A participant questioned whether there was a way, such as patents, to verify the number of products that have been commercialized. Mr. Murdock stated that he believes it is not possible because of the lack of authoritative information on what exactly is in commerce.

3.0 QUESTION AND ANSWER SESSION FOR KEY ISSUES

EPA provided meeting participants with an opportunity to make any additional comments or ask questions. This discussion was followed by a question and answer session focusing on key issues specifically identified by EPA in the Federal Register notice. A summary of these discussions is presented below.

3.1 General Questions and Answers

A meeting participant questioned whether the trade association representatives had a sense of the expected level of participation among their members. The American Chemistry Council declined to provide a specific number of companies that would participate, noting that commitments would be made a company level, however ACC members are generally supportive of the NMSP and are expected to make commitments. The NanoBusiness Alliance provided a similar response; indicating that it is still premature, but they expect members will volunteer to participate.

One participant noted several criticisms of the NMSP that were raised with respect to the similarities to the United Kingdom's program and their perceived lack of success. He asked the audience if there is anything EPA could do differently to ensure more successful participation. Sean Murdock (NanoBusiness Alliance) indicated that there may have been a lack of motivation because no deadlines existed and there was a perceived issue with protection of CBI in the UK, based on past incidents. Bill Gulledge (ACC) also noted that there is a difference in market size; therefore, although the actual number of participants is small, the percent of companies responding may not be.

A participant commented that the TSCA inventory paper was helpful and questioned whether EPA had given any further thought on use of SNURs. EPA responded that the paper's annexes discuss the TSCA authorities that address SNURs. There are criteria established by the statute that EPA must use to determine whether a use is a significant new use (i.e., understood as something that is not ongoing and is significant). EPA recognized that a challenge it will face if it considers a SNUR is defining the conditions that would merit "significant new use" that would trigger notification requirements. EPA will need to determine how that trigger would be defined in a general, overarching way. EPA also stated that it expects that experience gained through the NMSP and new chemical program will help inform the Agency on whether a SNUR is appropriate.

Another participant noted that the United Kingdom allowed academic institutions to participate in their voluntary program, where it appears that the U.S. is restricting non-commercial applications. EPA indicated that the program is not limited to engineered nanoscale materials manufactured or imported for commercial purposes. EPA referred participants to text in the proposed NMSP paper that allows non-commercial entities to participate and encouraged full participation. Another participant indicated that allowing submissions from academic institutions was an excellent idea, stating that most academics would like to publish test results in open literature but it is not common to publish "negative results". Participation in the NMSP would provide a venue to report negative results. Multiple participants suggested that EPA revise the NMSP description to clearly state that non-commercial entities could participate.

3.2 Key Questions and Answers

EPA outlined eleven specific key questions for stakeholders' consideration in the Federal Register notice. Jim Willis asked for the meeting participants to provide verbal responses to each of these questions, noting EPA requests written comments be submitted per instructions in the Federal Register notice. The questions, participant responses, and subsequent discussions are summarized below.

1. **Whether the data elements that have been identified in the NMSP are appropriate for nanoscale materials;**

    - A participant noted that the list is comprehensive and questioned how EPA would prioritize and use the data. He suggested that clarifying this may encourage participation. He also suggested that the question posed by EPA (whether the data elements are appropriate) cannot be answered without knowing how the information will be used.

      EPA replied that it intends to ask for information pertaining to all of the data elements. A subsequent evaluation of the responses will then determine exactly how it will be used.

      EPA added that the draft data elements were developed based on EPA risk assessors' experience evaluating data that are requested for the PMN review process. EPA also stated that initially, EPA only wants information that companies already possess.

    - EPA requested comments on the relevancy of these data elements with respect to nanoscale and questioned whether there were other data elements that may be more important, are easier to collect or are more valuable.

    - A participant noted that octanol/water coefficient and volatilization data are likely not needed.

    - EPA indicated that it may be valuable to review the Environmental Defense/Dupont Framework to compare lists of data elements and note that the OECD's working group efforts would also be considered.

    - A participant representing a mid-sized firm commented that the reporting format was "impressive and daunting" and resource intensive and that her firm's resources were already stretched thin given the European Commission's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) compliance requirements.

    - EPA questioned whether there was a subset of data elements that are most important and suggested possibly prioritizing these data elements.

    - One participant noted her expectation that companies would have all of this information prior to introducing a product/material into commerce. She also

requested that there be a formal way to substantiate data and claims to confirm their validity.

EPA indicated that the usual practice to substantiate data is to request method protocols and reference information to determine whether GLPs were followed. EPA would welcome such information to substantiate the value of the data. Additionally, EPA noted that it could request additional information if necessary.

- A participant questioned whether there were other examples of chemicals on the TSCA Inventory that are listed based on crystalline structures. EPA indicated that separate entries can exist if crystalline structures could be distinguished.

- Another participant questioned how the data would be used and raised concerns over "selective reporting." He suggested that if certain data elements were not provided that the submitter be required to state one of two reasons why: 1) Information not provided because it does not exist, or 2) Information not provided because of some other reason (e.g., CBI). Doing so would help to better characterize the state of the information.

  EPA noted that the proposed NMSP and data submission form encourages submitters to submit all information, including stating why data is not available.

2. Timing and phasing of submissions under the NMSP basic and in-depth programs and whether approaches for tiering data submissions are appropriate;

- EPA summarized comments provided earlier in the meeting that a timeframe from 3 to 9 months was suggested for the general program.

- One participant commented that the sooner EPA can collect the basic program information the better. She suggested that companies could document information they currently do not have and note when the information would likely be available.

- Another participant commented that the overall end objective of the basic program was to obtain information as quick as possible to get a sense of what materials are out there. The in-depth program should consider the key questions and the tests required to generate the information. The phases should be kept separate and work quickly to initiate the basic program.

- EPA suggested that a different timeline could be developed. As an example, rather than allowing two years for the basic program with interim and final evaluations, establish a three to nine month reporting period without an interim report and report on the overall assessment in 12 to 15 months. Companies could submit updated data later.

  EPA asked for input on how long it would take to assemble the right information to conduct a meaningful evaluation. EPA welcomes comments on what the appropriate cutoff dates should be for both submission of the data and EPA

reporting the findings of the evaluation.

- One participant questioned whether there were different objectives and requested confirmation that the NMSP was not a substitution for regulation and protecting human health and the environment.

  EPA responded that the NMSP would not continue indefinitely; rather, EPA would suggest a follow-on program which could have either or both a voluntary and regulatory program.

- A participant questioned whether summaries of raw studies, if written in different language, must be submitted in English, noting the resource requirements to translate documents may discourage participation.

  EPA indicated that summaries should be submitted in English, but it may not be necessary to translate the detailed studies. However, EPA may request translation of the raw studies if necessary.

- A participant questioned how EPA would measure success of the program – percent of companies or materials represented.

  EPA indicated that it will measure the success of the program by the quality of information that is received and whether it increases and informs EPA's knowledge. This evaluation will help EPA to reasonably determine what the next steps are.

- A participant questioned what data elements EPA will recommend companies submit and noted the difficulty of interpreting inconsistently formatted information.

  EPA responded that, for the basic program, EPA wants companies to provide whatever information is available. Whether there is a set of data that EPA would find most useful would most likely come about in the in-depth program for tiered data.

  EPA also noted that the OECD working group is working on this issue. EPA thinks the in-depth program and OECD frameworks will provide the means to provide a solid scientific understanding of these materials. EPA noted that it is possible that a preferred set of data elements could emerge.

- EPA noted several sources that are helping EPA better understand environmental concerns surrounding nanomaterials, including: EPA's White Paper; the Office of Research and Development's research framework; ongoing, internal risk assessment case studies; the upcoming peer consultation on material characterization; and reviews of nano-sized PMNs. All of these sources can help EPA to identify data gaps or improve EPA's understanding of the materials.

- A participant noted that NPPTAC recommendations addressed timing and he expressed concern about establishing a long-term program without deadlines. It was suggested that EPA should consider a second time period to capture people who were not ready or were not in the market when the basic program is initiated. The participant also suggested that the sign-up period for the basic program be very short.

- Another participant encouraged EPA to harmonize its efforts with OECD for the in-depth program to prevent companies from having to choose one program over the other and to encourage a parallel effort.

  EPA encouraged companies to work together on representative nanomaterials. EPA reminded participants that the in-depth program will include mechanisms to handle proprietary nanomaterials. EPA supports the convergence of programs and data for representative materials.

3. Who would participate in the NMSP and how to encourage participation, especially from small and medium sized enterprises;

- A participant questioned how EPA would know the extent of the participation level.

  EPA responded that the authority afforded by TSCA section 8(a) could require reporting. EPA could rely on its rulemaking authority to gain a comprehensive understanding.

- A participant suggested that EPA should actively advertise and market the NMSP. EPA could contact state industry councils to help spread the word.

- A participant reiterated his position on having concurrent voluntary and regulatory programs, and that, if done right, this approach could provide an incentive for participation by making it clear that if companies volunteer now, information requirements that will be imposed later will already be satisfied and recognize those companies that volunteer.

- EPA requested suggestions on the best way to reach businesses and target stakeholders that may not know they are stakeholders for potential workshops. EPA would like ideas on the types of training to hold before the program is initiated and commented that holding additional training workshops once the program is underway is a good idea.

- A participant reminded EPA of the success of the 33-50 program and the technical workshops that were held to increase understanding on how to participate.

4. **What criteria to use for NMSP program evaluation and views on the timing and nature of any reports the Agency may issue;**

Participants had no general comments regarding this question.

5. **How to engage industry and other stakeholders in the NMSP in-depth program and approaches for generating test data;**

Participants had no general comments regarding this question.

6. **The processes and roles for EPA, participants, and other stakeholders during development and evaluation of data for the in-depth program;**

Participants had no general comments regarding this question.

7. **Possible approaches for identification and use of alternative sources of data, in order to minimize the burden of information collection associated with the NMSP;**

- A participant urged harmonization of efforts among countries and noted that expert judgment will take precedence for the near term and EPA should determine how best to integrate expert judgment. The participant suggested developing a framework or quantifiable way to integrate data to make the information useful.

8. **Uses for the data submitted to EPA under the NMSP program;**

Participants had no general comments regarding this question.

- EPA commented that there is a focus on data use scenarios and EPA would like a reaction to those, as well as understanding other data uses.

9. **Issues relevant to scope, definitions and descriptions;**

- A participant questioned the distinction between films and coatings.

  A significant discussion ensued regarding various specific examples. EPA welcomed suggestions for a better way to characterize the scope.

- A participant noted that the American Chemistry Council provides a discussion of various nanotechnology terms on their Web site.

10. **The suitability of the approach for determining the TSCA Inventory status of nanoscale materials discussed in the Inventory paper; and,**

Participants had no general comments regarding this question.

11. Whether, in combination, the TSCA Inventory paper and the NMSP concept paper are sufficiently clear in how EPA plans at this time to address nanoscale materials that are new or existing chemicals under TSCA and the NMSP.

- Environmental Defense indicated that the documents are not adequate, noting and reiterating comments that were made earlier in the meeting.

- A participant indicated that EPA should clearly describe what its intent and current thinking is regarding the approach for addressing concerns surrounding nanomaterials (i.e., use the authorities listed, wait and see, start in parallel, etc.).

  EPA indicated that, at this time, no decisions on regulations have been made. However, EPA is committed to a collaborative process whereby stakeholders are given the opportunity to help shape the program, in part through meetings such as today's.

- A participant questioned clarification on TSCA section 8(e) reporting as it relates to nanoscale materials.

  EPA indicated that all materials subject to TSCA are subject to 8(e), including nanoscale materials. Further, EPA has received some 8(e) data on nanoscale materials, and if EPA determines additional information is needed, a request will be submitted to the company. EPA has consistently requested additional data about size and phenomena on nanoscale materials (both new and 8e submissions).

The meeting concluded by EPA reminding stakeholders that five weeks remain in the public comment period. EPA encouraged stakeholders to re-review the materials and to take advantage of clarifications and comments made today when preparing written comments for submission to the Docket. In addition, EPA requested that participants submit other materials that would inform the process and facilitate further understanding of all stakeholders. Charlie Auer indicated that EPA's intention is to launch the NMSP by the end of the calendar year.

Appendix A

AGENDA

Public Meeting on the Nanoscale Materials Stewardship Program

Holiday Inn Rosslyn at Key Bridge
Arlington, Virginia
August 2, 2007

Agenda

8:30 AM	Registration
9:00 AM	Welcome/Introductory Remarks – Jim Willis
9:10 AM	Keynote Remarks - Jim Gulliford
9:20 AM	Purpose – Nanoscale Materials Stewardship Program – Charlie Auer
9:40 AM	Carolyn Nunley Cairns, Consumers Union
	Bill Gulledge, American Chemistry Council
	Richard Denison, Environmental Defense
	Bernard Made, Environment Canada
10:40 AM	Break
11:00 AM	Scott Slaughter, The Center for Regulatory Effectiveness
	Terry Davies, Woodrow Wilson Center
	James Cooper, Synthetic Organic Chemical Manufacturers Association
	Igor Linkov, Intertox, Inc.
12:00 PM	Lunch
1:15 PM	Registered Speakers/Open Public Comments
2:45 PM	Break
3:00 PM	Register Speakers/Open Public Comments
4:15 PM	Wrap-up/Next Steps

Appendix B

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Environmental Protection Agency

Public Meeting on the Nanoscale Materials Stewardship Program

Holiday Inn Rosslyn at Key Bridge
Arlington, Virginia
August 2, 2007

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