

BEFORE THE NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

COMMENTS OF THE NANOTECHNOLOGY PANEL  
OF THE AMERICAN CHEMISTRY COUNCIL  
ON  
THE NANOSCALE SCIENCE, ENGINEERING, AND TECHNOLOGY  
SUBCOMMITTEE DOCUMENT  
ON  
ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH NEEDS  
FOR ENGINEERED NANOSCALE MATERIALS

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Notice of public meeting;  
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## EXECUTIVE SUMMARY

The Nanotechnology Panel (Panel) of the American Chemistry Council is pleased to submit these comments on the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee document, *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, which was publicly released on September 15, 2006 (NSET Document). The Panel is composed of companies engaged in the production, distribution, and/or use of chemicals with business interests in the products and applications of nanotechnology. The Panel's comments supplement the statement made by Mr. Paul D. Ziegler, the Panel Chair, at the January 4, 2007, public meeting that was convened by the National Nanotechnology Coordination Office.

The Panel, which is committed to the responsible development of nanotechnology, offers the following general comments on the NSET Document:

- The Panel supports and commends the NSET Subcommittee and its Nanotechnology Environmental and Health Implications Working Group on the NSET Document, which is a thorough and thoughtful review of the environmental, health, and safety (EHS) research and information needs related to the understanding and management of potential risks of engineered nanoscale materials.
- The Panel agrees that the NSET Document is a “foundational document” that can and should be used by the NSET Subcommittee and the federal agencies participating in the NNI to set and coordinate priorities for federal government-funded nanotechnology research programs.
- The Panel supports the NSET Subcommittee's three principles for identifying and prioritizing EHS research: (1) prioritize based on the value of information; (2) leverage international and private sector research efforts; and (3) use adaptive management for nanomaterial EHS research.

Also, as stated in these comments, the Panel offers specific comments:

- Prioritizing among the various EHS research and information needs is essential;
- NNI should continue to work with standard setting organizations and others to advance instrumentation, metrology, and analytical methods development;

- NNI should consider compiling a listing of ongoing and completed EHS research and making such a compilation broadly available to ensure important research is communicated quickly and accurately;
- Research on the environmental transport and fate of nanomaterials is needed and should be prioritized accordingly;
- NNI should ensure that databases believed to report on consumer products containing nanomaterials are accurate to ensure the public is well informed; and
- NNI should carefully review information on nanoscale materials resulting from pertinent voluntary initiatives, including Organization for Economic Cooperation and Development and related programs, before endeavoring to formulate risk management approaches to ensure any such approach is fully reflective of the best and most recent information.

In summary, the Panel believes the NSET Document is an excellent compilation of the current EHS research needs for engineered nanoscale materials.

## TABLE OF CONTENTS

EXECUTIVE SUMMARY .....	i
TABLE OF CONTENTS.....	iii
INTRODUCTION .....	1
I. THE NANOTECHNOLOGY PANEL IS COMMITTED TO THE RESPONSIBLE DEVELOPMENT OF NANOTECHNOLOGY.....	2
II. PANEL COMMENTS ON THE NSET DOCUMENT.....	4
A. General Comments.....	4
B. Prioritizing Among the Various EHS Research and Information Needs Is Essential .....	6
C. NNI Should Continue to Work with Standard Setting Organizations and Others to Advance Instrumentation, Metrology, and Analytical Methods Development.....	8
D. NNI Should Consider Compiling a Listing of Ongoing and Completed EHS Research and Making Such a Compilation Broadly Available to Ensure Important Research is Communicated Quickly and Accurately.....	9
E. Research on the Environmental Transport and Fate of Nanomaterials Is Needed and Should Be Prioritized Accordingly.....	10
F. NNI Should Ensure That Databases Believed to Report on Consumer Products Containing Nanomaterials Are Accurate to Ensure the Public Is Well Informed.....	10
G. NNI Should Carefully Review Information on Nanoscale Materials Resulting from Pertinent Voluntary Initiatives.....	11
CONCLUSION.....	12

## INTRODUCTION

The Nanotechnology Panel (Panel) of the American Chemistry Council is pleased to submit these comments on the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee document, *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials* (NSET Document), which was publicly released on September 15, 2006.<sup>1</sup> The Panel is composed of companies engaged in the production, distribution, and/or use of chemicals with business interests in the products and applications of nanotechnology.<sup>2</sup> The Panel's comments on the NSET Document supplement the statement made by Mr. Paul D. Ziegler, the Panel Chair, at the public meeting convened by the NNCO on January 4, 2007.<sup>3</sup>

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<sup>1</sup> In its December 8, 2006, *Federal Register* notice announcing the January 4, 2007, public meeting, the National Nanotechnology Coordination Office (NNCO) indicated that written or electronic comments on the NSET Document could be submitted via the National Nanotechnology Initiative's (NNI) website until January 31, 2007. 71 Fed. Reg. 71196 (Dec. 8, 2006).

<sup>2</sup> Panel member companies include: Air Products and Chemicals, Inc., Arkema, Inc., BASF Corporation, Bayer MaterialScience, LLC, Cytec Industries Inc., Degussa Corporation, Dow Chemical Company, DuPont, Elementis Specialties, Honeywell, PPG Industries, Inc., Proctor & Gamble Company, Oxonica, Ltd., Rohm and Haas Chemicals, and Sasol North America, Inc.

<sup>3</sup> See Statement of Paul D. Ziegler, PPG Industries, on behalf of the American Chemistry Council Nanotechnology Panel before the National Nanotechnology Coordination Office (Jan. 4, 2007), available at [https://nnco.nano.gov/public\\_ehs/uploads/Ziegler\\_for\\_ACCNanotechnologyPanel\\_EHS\\_20070104NG.pdf](https://nnco.nano.gov/public_ehs/uploads/Ziegler_for_ACCNanotechnologyPanel_EHS_20070104NG.pdf).

I. THE NANOTECHNOLOGY PANEL IS COMMITTED TO THE RESPONSIBLE DEVELOPMENT OF NANOTECHNOLOGY

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The Panel was formed in 2004 to foster the responsible development and application of nanotechnology, to coordinate nanotechnology environmental, health, and safety (EHS) 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<sup>®</sup> Program to ensure that the commercialization of nanoscale materials proceeds in a way that protects workers, the public, and the environment.

The Panel recognizes that nanotechnology applications offer significant societal and sustainable development advancements, many of which could provide direct public health and environmental benefits that could greatly enhance the quality of life. Nanotechnology products offer, for example, the potential for improved energy production, environmental remediation, and pollution prevention, among many other benefits that could greatly enhance the quality of life. The Panel shares the federal government's goal, however, of identifying nanotechnology's potential risks to ensure protection of human health and the environment, and believes that the responsible development will help assure the public that nanomaterials are being developed in a way that identifies and minimizes potential risks to human health and the environment.

In this regard, the Panel and Environmental Defense (ED) issued a Joint Statement of Principles in 2005 that reflects the parties' shared view of several core principles on which a governmental program for addressing potential risks of nanoscale materials should be premised.<sup>4</sup> The Panel takes this opportunity to restate them below:

- 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

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<sup>4</sup> A complete copy of the Joint Statement of Principles is available at [http://www.americanchemistry.com/s\\_acc/bin.asp?CID=654&DID=2761&DOC=FILE.PDF](http://www.americanchemistry.com/s_acc/bin.asp?CID=654&DID=2761&DOC=FILE.PDF).

also assess the appropriateness of or need for modification of existing regulatory frameworks.

## II. PANEL COMMENTS ON THE NSET DOCUMENT

The Panel offers the following comments on the NSET Document.

### A. General Comments

The Panel supports and commends the NSET Subcommittee and its Nanotechnology Environmental and Health Implications (NEHI) Working Group on the NSET Document, which is a thorough and thoughtful review of the EHS research and information needs related to the understanding and management of potential risks of engineered nanoscale materials. The Panel agrees that the NSET Document is a “foundational document” that can and should be used by the NSET Subcommittee and the federal agencies participating in the NNI to set and coordinate priorities for federal government-funded nanotechnology research programs. In particular, the Panel supports the NSET Subcommittee’s three principles for identifying and prioritizing EHS research: (1) prioritize based on the value of information; (2) leverage international and private sector research efforts; and (3) use adaptive management for nanomaterial EHS research.<sup>5</sup>

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<sup>5</sup> NSET Document at 9-10.



In the Panel's view, prioritizing research based on the value of the information to be derived from it is critically important. The Panel also encourages the NNCO to coordinate its research strategies with the activities of the Organization for Economic Cooperation and Development's (OECD) Working Party on Manufactured Nanomaterials (WPMN), and in this vein, the Panel notes that the WPMN has identified the following six specific projects to focus on in 2007:

1. Developing a database on EHS research;
2. Identifying and coordinating EHS research strategies;
3. Testing of a representative set of manufactured nanomaterials;
4. Reviewing and developing test guidelines for testing;
5. Sharing information on voluntary and regulatory programs; and
6. Sharing information on risk assessment and exposure measurement.

With respect to the third prioritization principle, the Panel applauds the NSET Subcommittee's recognition of the importance of "adapt[ing] research strategies in accordance with emerging R&D directions."<sup>6</sup> It is imperative, the Panel believes, for ongoing and planned research to be continually monitored and (re)assessed in light of the latest research developments. For example, if a newly completed study were to demonstrate that a previously perceived effect does not in fact occur, then planned research on that effect should be reassessed in light of the study's finding. EHS research must be nimble, and while priorities most certainly have to be set, they, along with the associated funding levels to support the prioritized research,

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<sup>6</sup> NSET Document at 10.

must not be set in stone. Rather, the federal agencies funding and/or conducting research, as well as other governments, the private sector, and the research community, must have the ability to make mid-course corrections and adapt as necessary.

Implicit in this essential adaptability principle, moreover, is the need to adjust funding levels to reflect the realities and developments of the day. Given the extensive research and information gaps identified in the NSET Document, the Panel urges the NNCO to acknowledge that there is a pressing need *today* for increased federal funding for EHS research.

Finally, the Panel notes that the NSET Document refers in several places to nanomaterial research being conducted by the Department of Defense (DOD).<sup>7</sup> Little is currently known about this DOD research, and the Panel believes that, to the extent feasible, more information on it should be provided by the NNCO.

B. Prioritizing Among the Various EHS Research and Information Needs Is Essential

While the NSET Document provides a comprehensive description of the EHS research that is needed to enable sound risk assessment and risk management of engineered nanoscale materials and the products that incorporate them, it makes no attempt to prioritize among those various needs. Prioritization is key, and in the Panel's view, should be carried out by the NSET Subcommittee and NNI federal agencies as expeditiously as possible.

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<sup>7</sup> See NSET Document at 16, 21, and 31.

The Panel specifically urges the NSET Subcommittee and NNI agencies to prioritize the EHS research needs according to the following hierarchy:

- chemical identification and characterization and metrology;
- exposure, fate, and effects;
- risk assessment;
- work place practices/best manufacturing practices; and
- green manufacturing/end-use applications.

This hierarchy, which the Panel has urged the U.S. Environmental Protection Agency (EPA) to adopt in its forthcoming final *Nanotechnology White Paper*, provides a logical structure to maximize the consistency, timeliness, and value of the information generated by research.<sup>8</sup>

The Panel believes that the development of definitions and terminology for determining what is a “nanomaterial” is a crucial first step in defining the universe of materials subject to evaluation in any risk assessment program. This issue should be accorded the highest priority, and if possible, a consensus reached as quickly as possible among the various entities evaluating nanotechnology and nanomaterials.

With respect to risk assessment research, the Panel wishes to emphasize that traditional risk assessment approaches are widely thought to be appropriate for the risk

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<sup>8</sup> The Panel notes, though, that the hierarchy may have to be adjusted for different types of representative nanoscale materials.

management of nanomaterials. This view is evidenced in a variety of contexts. For example, in the external review draft *Nanotechnology White Paper*, EPA states that “we assume that the [National Academy of Science] paradigm is appropriate for the assessment of nanomaterials.”<sup>9</sup>

C. NNI Should Continue to Work with Standard Setting Organizations and Others to Advance Instrumentation, Metrology, and Analytical Methods Development

The Panel encourages the NNCO and relevant NNI agencies to continue working actively with the different standards development organizations, trade groups, and other entities that are addressing nanomaterials terminology and nomenclature issues. The NNCO and NNI agencies should remain actively involved in all of these efforts.

In addition, the Panel supports the continued collaboration of the federal government, industry, non-governmental organizations, and academia in responding to the research needs identified in the NSET Document that are related to analytical tools and methods, particularly the development of methods for detecting nanomaterials in biological matrices, the environment, and the workplace. The Panel notes in this regard the Nanoparticles Benchmarking Occupational Health, Safety, and Environment Program, a useful illustration of precisely this type of innovative and forward thinking collaboration. The program consists of a consortium of companies, many of which are Panel members, which joined together to address common

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<sup>9</sup> E.g., EPA, Nanotechnology Workgroup, Science Policy Council, Nanotechnology White Paper – External Review Draft (Dec. 2, 2005) at 33 (“At this point in time, we assume that the [National Academy of Sciences] paradigm is appropriate for the assessment of nanomaterials.”), available at [http://www.epa.gov/osa/pdfs/EPA\\_nanotechnology\\_white\\_paper\\_external\\_review\\_draft\\_12-02-2005.pdf](http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf).

analytical needs to measure airborne concentrations and particle sizes and to assess effectiveness of controls. Three work products are underway: a chamber test to define aerosols and monitor aerosol behavior as a function of time; a prototypical instrument to measure particle concentration in workplace ambient air in discrete particle size range; and the ability to measure penetration of nanoparticles from an air stream through filters, gloves, or protective clothing.

D. NNI Should Consider Compiling a Listing of Ongoing and Completed EHS Research and Making Such a Compilation Broadly Available to Ensure Important Research Is Communicated Quickly and Accurately

The Panel believes that a starting point for future research in the area of nanomaterials and their impact on human health should be an effort to compile, in one central, publicly accessible database, all completed research as well as all research that is currently underway. Among other things, such a compilation would be a valuable means to avoid duplication and thus help ensure that limited resources are fully utilized and strategically targeted.

While the Panel concurs with all of the human health-related research needs identified by the NSET Subcommittee, the Panel considers an understanding of the absorption and transport of nanomaterials throughout the body as the area deserving the highest priority. Research on test methods and models to predict human responses to nanomaterials also merits a high priority, as does the development of methods for quantifying and characterizing exposure to nanomaterials.

E. Research on the Environmental Transport and Fate of Nanomaterials Is Needed and Should Be Prioritized Accordingly

As the NSET Document confirms, EPA and the National Institute for Occupational Safety and Health (NIOSH), among others, are now funding much needed research in the area of environmental transport and fate, and the Panel fully supports these efforts. Additional research is needed to evaluate the application of existing ecological effects test methods and protocols to nanoscale materials.

F. NNI Should Ensure That Databases Believed to Report on Consumer Products Containing Nanomaterials Are Accurate to Ensure the Public Is Well Informed

In the area of health and environmental surveillance, the Panel strongly supports prioritizing the development of methods for detecting nanomaterials in biological matrices, the environment, and the workplace. The Panel also believes that NNI should seek to ensure that existing databases on nanotechnology-based consumer products are accurate and current to the greatest extent possible, thus helping to ensure that the public is well informed.

G. NNI Should Carefully Review Information on Nanoscale Materials Resulting from Pertinent Voluntary Initiatives

The Panel, which agrees with NSET that “[a]n initial priority” should be “evaluation of risk management techniques for workers in manufacturing and research facilities and for their potential applicability to larger populations,”<sup>10</sup> fully supports research on the efficacies of personal protective equipment against nanomaterials, and observes that NIOSH should play an integral role in such research. In addition, the Panel encourages projects aimed at understanding how life cycle assessment may be suitable and adaptable to nanomaterials.

Whenever possible, the NNCO and NNI agencies should strive to gather information on risk management approaches from voluntary programs (*e.g.*, the NIOSH Information Exchange and the Nanoscale Materials Stewardship Program expected to be launched later this year by EPA) as well as from other organizations (*e.g.*, OECD and the United Kingdom Department for Environment, Food and Rural Affairs, which commenced a Voluntary Reporting Scheme for engineered nanoscale materials in September 2006). Ultimately, the Panel believes that the formulation of risk management approaches for nanomaterials must be preceded by a thorough information-gathering effort and by implementation of the various projects highlighted in Chapters 2-5 of the NSET Document.

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<sup>10</sup> NSET Document at 43.

## CONCLUSION

The Panel believes the NSET Document is an excellent compilation of the current EHS research needs for engineered nanoscale materials. So that the various needs identified in the document can be addressed in a suitable and timely manner, the Panel encourages the NNCO, the National Science and Technology Council, and the NSET Subcommittee to pursue in a coordinated fashion appropriate federal funding for nanotechnology EHS research. In addition, the Panel encourages appropriate federal oversight of federally-funded research, since in the absence of such oversight there is an ever-present risk of delay and duplication.

The Panel appreciates and thanks the NNCO for this opportunity to comment.