

BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

COMMENTS OF THE NANOTECHNOLOGY PANEL
OF THE AMERICAN CHEMISTRY COUNCIL
ON THE NANOTECHNOLOGY WHITE PAPER EXTERNAL REVIEW DRAFT

Notice of Availability of the
Nanotechnology White Paper
External Review Draft
70 Fed. Reg. 75812 (Dec. 21, 2005)

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EXECUTIVE SUMMARY

The Nanotechnology Panel (Panel) of the American Chemistry Council submits these comments on the United States Environmental Protection Agency's (EPA) December 21, 2005, *Federal Register* notice announcing the availability of and seeking comment on the *Nanotechnology White Paper External Review Draft* (Draft White Paper) prepared by the Nanotechnology Workgroup of EPA's Science Policy Council. 70 Fed. Reg. 75812. The Panel consists of companies that are engaged in the manufacture, distribution, and/or use of chemicals and have a business interest in the products of nanotechnology.

The Panel compliments EPA on the Draft White Paper. It is well written, comprehensive, and useful. As described more fully in these comments, the Panel supports the key recommendations set forth in the document and urges EPA to prioritize them along the lines suggested. Specifically, the Panel believes that the occasion of the issuance of the Nanotechnology White Paper offers EPA a tremendous opportunity to present these recommendations in a cogent and compelling, priority-based order that reflects a logical and science-based approach to the responsible development of nanotechnology. The Panel proposes the following revised order: collaboration; cross-agency workgroups; coordination; research; overarching risk assessment needs; training; pollution prevention and environmental stewardship.

The Panel also believes that within the research recommendations, EPA should reprioritize its recommendations. Specifically, the Panel urges EPA to prioritize its research needs in the following order: chemical identification and characterization; metrology; exposure, fate, and effects; risk assessment; work place practices/best manufacturing practices; and green manufacturing/end use applications.

The Panel also notes a number of specific comments and accordingly urges applicable changes and/or corrections.

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INTRODUCTION

The Nanotechnology Panel (Panel) of the American Chemistry Council submits these comments on the United States Environmental Protection Agency's (EPA) December 21, 2005, *Federal Register* notice announcing the availability of and seeking comment on the *Nanotechnology White Paper External Review Draft* (Draft White Paper) prepared by the Nanotechnology Workgroup of EPA's Science Policy Council. 70 Fed. Reg. 75812. The Panel consists of companies that are engaged in the manufacture, distribution, and/or use of chemicals and have a business interest in the products of nanotechnology.¹

I. THE NANOTECHNOLOGY PANEL AND ITS COMMITMENT TO THE RESPONSIBLE DEVELOPMENT OF NANOTECHNOLOGY

The Panel was formed in 2004 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.

¹ Panel member companies include: Air Products and Chemicals, Inc., Arkema Inc., BASF Corporation, Bayer Corporation, Ciba Specialty Chemicals Corporation, Degussa Corporation, Dow, DuPont, Elementis Specialties, PPG Industries, Inc., Procter & Gamble, Rohm and Haas Company, Sasol North America, Inc., and Southern Clay Products, Inc.

The Panel recognizes that nanotechnology applications offer significant societal and sustainable development advancements, many of which could provide direct environmental benefits. 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 EPA'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 Principles² 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. As many of the principles the Panel and ED jointly embrace are pertinent to the issues addressed in the Draft White Paper, we 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.

² A copy of the Joint Statement of Principles is found at Attachment 1.

- 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.

II. PANEL COMMENTS ON THE EXTERNAL REVIEW DRAFT WHITE PAPER

The Panel compliments EPA on the Draft White Paper. It is well written, comprehensive, and useful. As described more fully in these comments, the Panel supports the key recommendations set forth in the document and urges EPA to prioritize them along the lines suggested. The Panel also notes a number of specific comments.

A. General Comments

The Panel appreciates that EPA included representatives from all EPA program offices in preparing the Draft White Paper and believes that as a result, the document better reflects the full range of potential environmental applications that nanotechnology offers. The Panel also believes that the Draft White Paper does a good job of outlining many of the issues pertaining to nanotechnology, and strikes an appropriate balance between expressing concerns regarding potential hazard and risk and also acknowledging the technological, environmental, and societal benefits nanotechnology offers.

The Panel also commends EPA for its leadership in this area and for undertaking the preparation of the Draft White Paper. The Panel is aware of the many competing priorities vying for limited EPA resources and time, and appreciates EPA's deployment of resources on the important topic of nanotechnology.

The Panel offers two overarching comments with regard to EPA's key recommendations. First, the recommendations do not appear to be set forth in any particular order. For example, pollution prevention and environmental stewardship is the first recommendation in Section 6.0 (Recommendations), which could give rise to the inference that this is EPA's first priority. Panel member companies are deeply committed to pollution prevention and product stewardship. Nonetheless, the Panel believes that this recommendation, and others identified by EPA, must be informed by and can only proceed based on a clearer, knowledge-based understanding of basic concepts such as chemical identification, risk

characterization, and related topics. This, in turn, can only arise from more global collaboration and domestic agency cooperation on nanotechnology-related issues that would need to be much further along than they now are. The Panel thus urges EPA to prioritize the recommendations along the following lines: collaboration; cross-agency workgroups; coordination; research; overarching risk assessment needs; training; and pollution prevention and environmental stewardship.

Second, the Panel believes that the research recommendations should be prioritized according to the following order: chemical identification and characterization; metrology; exposure, fate, and effects; risk assessment; work place practices/best manufacturing practices; and green manufacturing/end use applications. The Panel also supports continuing work on environmental fate and exposure and the development of models that can be used to generate rapidly information in the absence of experimental data.

The Panel believes that EPA's commitment to the responsible development of nanotechnology can best be fulfilled by leveraging, to an even greater extent, interaction with other federal, state, and international agencies. The Panel firmly believes that other federal agencies, including the National Institute for Occupational Safety and Health (NIOSH), the Food and Drug Administration (FDA), state agencies, and international agencies, such as the Organization for Economic Cooperation and Development (OECD), have much to offer and must be an integral part of the global development of nanotechnology to ensure that limited resources are deployed effectively, research priorities are addressed first, and regulatory frameworks evolve in a way that maximizes international harmonization.

B. Specific Comments

The Panel offers the following specific comments on the Draft White Paper. For clarity, the Panel notes the specific section, page number, and line number of the reference in the Draft White Paper, followed by the Panel's comment.

- **1.2 Nanotechnology Defined, page 4, line 26** -- The Panel concurs with EPA that the “definition of nanotechnology does not include unintentionally produced nanomaterials, nano-sized particles, or materials that occur naturally in the environment.” The Panel believes that the National Nanotechnology Initiative (NNI) definition of nanotechnology should be used, which excludes unintentionally produced nanomaterials.

- **1.3 Why Nanotechnology Is Important to EPA, page 9, line 11, and page 10, line 2** -- EPA notes here that nanomaterials have promising environmental applications, and points to nano-sized cerium oxide developed to decrease diesel emissions. Elsewhere in the document, however, on page 57, EPA describes one study involving a cerium additive that has shown cerium “to significantly alter the physicochemistry of diesel exhaust emissions resulting in increased levels of air toxic chemicals such as benzene, 1,3-butadiene, and acetaldehyde.” The Panel urges EPA to harmonize these sections of the draft document.

In the same section at page 10, line 2, EPA states “Inhaled nanoparticles may become lodged in the lung, and the high durability and reactivity of some nanomaterials raises issues of their fate in the environment.” The Panel submits that it may be more accurate to state that “Some inhaled nanoparticles may become...” It is by no means clear that all nanomaterials have the potential to become lodged in the lung.

- **1.4 What EPA is Doing with Respect to Nanotechnology, page 10, line 28** -- EPA notes that it is “initiating the development of a voluntary pilot program for the evaluation of nanomaterials and reviewing of nanomaterial new chemical submissions in the Office of Pollution Prevention and Toxics.” The Panel supports the development of a voluntary program along the lines the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) outlined in its November 2005 *Overview of Issues Document*. The Panel urges EPA to take whatever steps are necessary to move forward the development of the voluntary program, and renews its commitment to assist EPA in this regard.

- **1.5.2 Efforts of Other Stakeholders, page 12, line 12** -- The Panel appreciates reference to its efforts, but asks that EPA revise the reference to state the Panel's correct name, which is the American Chemistry Council Nanotechnology Panel, not "committee."
- **4.3.8 Interactions Between Nanomaterials and Organic or Inorganic Contaminants: Effects and the Potential for Practical Applications, page 41, line 4** -- EPA states in the Draft White Paper that "Nanoscale materials are typically more reactive than larger particles of the same material. This is true especially for metals and certain metal oxides." The Panel is not aware of data that support this statement or that suggest that nano-sized metals and metal oxides are more reactive relative to their bulk-sized counterparts. The Panel believes this is erroneous and thus suggests that this statement be deleted.
- **4.3.9 Applicability of Current Environmental Fate and Transport Models to Nanomaterials, page 42, line 18** -- EPA notes that "the most useful modeling tools for exposure assessment of nanomaterials are likely to be found not in the area of environmental fate of specific organic compounds (more precisely, prediction of their transport and transformation), rather in fields in which the focus is on media-oriented pollution issues: air pollution, water quality, ground water contamination, etc. A survey of such tools should be made and their potential utility for nanomaterials assessed." The Panel concurs that such a survey would be very useful and urges EPA to undertake its preparation.
- **4.5.3.1 Occupational Exposure, page 45, line 15 through page 46, line 3** -- The Panel concurs with EPA's reliance upon Luther (2004) that the risk of particle release during production is low due to the fact that most production processes take place in closed systems. Similarly, the Panel concurs that release and exposure to nanomaterials is expected to be low once they have been incorporated into a formulation and linked to a matrix.
- **4.5.3.2 Release and General Population Exposure, page 46, lines 14 and 24** -- EPA notes that "[g]eneral population exposure may occur from environmental releases from the production and use of nanomaterials and direct use of products containing nanomaterials" (line 14). This statement should be qualified along the lines set forth in the section immediately above it. Namely, EPA should note that exposure to nanomaterials from releases from production are expected to be low and thus contribute marginally, if at all, to the total exposures from chemicals to the general public. Taken out of context, this passage could be the cause of unnecessary concern.

Similarly, the Panel does not believe that EPA needs to include the last sentence in this section relating to natural disasters and terrorist attacks (line 24). Naturally, disasters of this nature will of course heighten the probability of releases of materials into the environment. Because these events are always theoretically possible, the inclusion of this sentence in the document adds little and may be the source of unnecessary concern.

- **4.6.2 Adequacy of Current Toxicological Database, page 52, line 12 --** EPA states “[t]he Agency’s databases on the health effects of particulate matter (PM), asbestos, silica, or other toxicological databases of similar or larger sized particles of identical chemical composition (US EPA, 2004; US EPA, 1986; US EPA 1996) should be evaluated for their potential use in conducting toxicological assessments of intentionally produced nanomaterials. The toxicology chapter of the recent *Air Quality Criteria for Particulate Matter* document cites hundreds of references describing the health effects of ambient air particulate matter including ultrafine ambient air (PM_{0.1}), silica, carbon, and titanium dioxide particles (US EPA 2004). However, it is important to note that ambient air ultrafine particles are distinct from intentionally produced nanomaterials since they are not purposely engineered and represent a physicochemical and dynamic complex mixture of particles derived from a variety of natural and combustion sources.”

The Panel agrees that EPA’s databases on the health effects of particulate matter should be evaluated for their potential use in conducting toxicological assessments of nanomaterials. The Panel also urges EPA, however, to take care in extrapolating these data to engineered nanoparticles. In many cases, the Panel believes that such extrapolation may not be scientifically justifiable.

III. PANEL COMMENTS ON KEY RECOMMENDATIONS

As noted above, the Panel concurs with EPA’s key recommendations as set forth in Section 6.0 of the Draft White Paper, and as summarized on page 2. The Panel believes, however, that the recommendations should be presented in priority order and to prioritize them along the lines suggested above. Specifically, the Panel urges EPA to present the recommendations in the following revised order: collaboration; cross-agency workgroups; coordination; research; overarching risk assessment needs; training; and pollution prevention and

environmental stewardship. The Panel offers specific comment on each of the key recommendations below in the order in which they are presented in the Draft White Paper.

- **Pollution Prevention, Stewardship, and Sustainability** -- The Panel encourages EPA to continue its efforts to identify and use nanotechnology in ways that provide benefits to the environment, including remediation of contamination. The Panel supports efforts to work with other stakeholders, (*i.e.*, NGOs, SMEs, academia, etc.) to identify ways to achieve success that are effective and consistent with ACC Panel members' commitment to Responsible Care®, product stewardship, and sustainability.

- **Research** -- The Panel agrees with the recommendation that EPA focus on the research topics specifically enumerated in the Draft White Paper. EPA is well positioned to make a key contribution in facilitating stakeholder collaboration to achieve common goals and finding a balance between the desire for any information on nanotechnology and the scientific information needed to make scientifically sound risk assessments. EPA is positioned to take a leadership role in the identification and characterization of nano-sized materials and in using terminology appropriately. EPA notes that the identification and characterization of chemical substances and materials is an “important first step in assessing their risk.” The Panel concurs. Not only is this step important, it is critical to making progress in the development of the science and its application to the risk assessment of nanomaterials. EPA is mindful of the importance of working with domestic (*e.g.*, ASTM, ANSI, NNI) and international (*e.g.*, OECD, BIAC, ISO) initiatives in this regard, and in participating in these groups. The Panel appreciates that EPA is seeking input from many different entities. At an appropriate time, the Panel believes it would be helpful for EPA to clarify how it views terminology from a regulatory perspective.

The Panel supports continuing work on environmental fate and exposure and the development of models that can be used to generate rapidly information in the absence of experimental data. The Panel recommends, that EPA prioritize its research according to the following order: chemical identification and characterization; metrology; exposure, fate, and effects; risk assessment; work place practices/best manufacturing practices; and green manufacturing/end use applications.

- **Risk Assessment** -- The Panel supports EPA's conclusion that existing risk assessment procedures are sound and can form the basis for the assessment of nanomaterials. The Panel also agrees that selecting

materials for case studies will help all stakeholders, and the Panel is willing to work on this with EPA. EPA states in the Draft White Paper that “EPA generally follows the risk assessment paradigm described by the National Academy of Sciences (NAS) (NAS/NRC, 1983 1994). The overall risk assessment approach used by EPA for conventional chemicals is thought to be generally applicable to nanomaterials.” The Panel supports the use of the NAS risk assessment paradigm of nanomaterials, and sees no basis or need for a risk assessment approach that is unique to nanomaterials.

- **Collaboration and Leadership** -- The Panel commends EPA for the leadership it has shown thus far in the nanotechnology area, and encourages EPA to continue its efforts. The Panel looks forward to working with EPA as it has recently through its participation in public meetings and the NPPTAC Interim Ad Hoc Work Group on Nanoscale Materials. The Panel also encourages EPA to help the many stakeholders holding a diversity of views to find a balance between the desire to know as much as can be known about nanomaterials, and to develop a knowledge base that is not so onerous in scope that development of these materials, and the societal benefits they will bring, will be stifled. In addition, the Panel urges EPA to collaborate closely with other federal agencies, to share work product and results, and to ensure consistency as much as possible given the diversity of laws and regulations that pertain to nanomaterials. Many companies are regulated under these other laws and by the agencies that administer them. These companies, which include members of the Panel, may be useful in assisting EPA in developing information and contacts to support and facilitate the development of these collaborations.

- **Cross-Agency Workgroup** -- The Panel supports the convening of a cross-agency group to foster information sharing, and supports encouraging other agencies to assume a leadership role in topic areas where those agencies have particular strengths. EPA recommends that various EPA offices take the lead on certain activities and collaborations. It is admirable that EPA is showing this high level of commitment to nanotechnology. The Panel believes, however, that EPA’s commitment to nanotechnology may be maximized by leveraging the commitment of other federal agencies with which the burden should be shared and that have much to contribute. For example, some nanomaterials have been proposed to be used as drug delivery systems as was noted in the Draft White Paper. If these nanomaterials are under evaluation at the FDA, it is likely that some of the information that is required to assess the performance of these delivery systems will also be useful to EPA in assessing these nanomaterials in other areas. Another example is the work being done by NIOSH and the Occupational Safety and Health Administration (OSHA) regarding workplace safety. The Panel suggests

that the cross-agency group share information and share responsibilities. The Panel also supports EPA working globally with other international agencies and/or groups to coordinate research to leverage efficiently and avoid duplication.

- **Training** -- The Panel supports EPA activities that increase the knowledge of its staff regarding nanotechnology. A high level of knowledge will support sound decision-making. Further, the Panel requests that EPA publicly identify, when possible, the training received by EPA staff. The Panel also requests that if EPA provides internal training that, when possible, the same training is offered to interested stakeholders. A model for the external training could be the Sustainable Futures program. All stakeholders could benefit from additional training. Additionally, such sessions could also serve as opportunities for stakeholders to meet and share information. The Panel includes companies that employ scientists, engineers, and other experts in nanotechnology who could provide training to EPA staff on targeted topics to expand EPA's knowledge base, enhance its understanding of this fast-changing emerging technology and provide general assistance to EPA.

CONCLUSION

For all the reasons discussed above, the Panel urges EPA to consider the comments and suggestions offered by the Panel in preparing the Nanotechnology White Paper in final, and thanks EPA for this opportunity to comment.

Attachment

Attachment 1

Environmental Defense and American Chemistry Council Nanotechnology Panel

Joint Statement of Principles

Nanotechnology applications promise significant societal and sustainable development advancements, many that could provide direct environmental benefits. Nanotechnology products offer, for example, the potential for improved energy production, environmental remediation, and solar power production, among many other benefits. But it is also important to identify and better understand nanotechnology's potential risks up front to ensure protection of health and the environment, particularly in light of initial studies demonstrating that some nanomaterials have hazardous properties.

The U.S. Environmental Protection Agency's May 10, 2005, *Federal Register* notice announces the scheduling of a public meeting and seeks information on a potential "voluntary pilot program" on nanoscale materials. Without taking a joint position on the merits of such a program, Environmental Defense and the American Chemistry Council's Nanotechnology Panel agree on several fundamental principles on which a governmental program for addressing potential risks of nanoscale materials should be premised.

We believe:

- 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.