UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

[Date]

EPA-SAB-09-xxx

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Particulate Matter Research Centers Program Advisory Report: An SAB Advisory Report

Dear Administrator Johnson:

The EPA Science Advisory Board (SAB) Particulate Matter (PM) Research Centers Advisory Panel met on October 1-2, 2008 to consider questions posed by EPA on the future directions of its PM Research Centers program. The Panel concluded that this program has been very successful and that its continuation, especially in a form that would begin to move this area of research into integrated assessments of multiple air pollutants, would be of great value. This report provides the SAB's advice in response to EPA's three charge questions, which addressed the contributions of the existing program, multiple pollutant strategies and Center structure.

In response to Charge Question 1, the SAB concluded that the existing PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The advances have been extensively cited in EPA documents supporting policy decisions and have been influential in the scientific community. The SAB recommends that the EPA continue to use a variety of performance indicators to assess Center performance and recommends additional measures be added to those already used in the Center evaluations. Additional measures should broaden the range of indicators of Center impacts on the scientific community and the range of indicators that document the extent to which Center work is used in support of Agency decisions. Additional measures should also characterize the extent to which Center resources are supplemented by research support from other EPA programs and from other governmental and non-governmental research programs.

The SAB also concluded that the Centers Program has produced benefits over those that would be expected in traditional STAR grant mechanisms involving individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits included flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The SAB recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also noted that both Centers and individual or small team research initiatives are essential.

In response to Charge Question 2, the SAB concluded that the Centers have already begun to address broad sets of air pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the future Center activities. Specifically, the SAB recommends that multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, toxicology, and epidemiology. Although the SAB generally agreed with the Agency's suggestion that organizing its multi-pollutant efforts around sources could be useful, it cautioned that an over-emphasis only on near-roadway exposures in such efforts could under-represent the importance of other sources and the atmospheric transformation of their emissions that are significant contributors to exposure. The Panel also concluded that the future Center activities could usefully address another important and broad direction: the regional differences in pollutant mixtures, and potential differences in health effects.

Finally, in response to Charge Question 3, regarding recommendations for changes to the structure of the PM Centers, the SAB recognized the successes of the PM Centers program over its history. Because of the Program's success, some panel members questioned the need to make major changes in the structure of the program. The SAB offers some comments in this report on the strengths and weaknesses of several structural changes that were proposed by the EPA, as well as additional comments on important issues idenfitied by the review Panel. Among these are that: a) the notion that all Centers should study identical research topics was not supported; b) requiring all Centers to have a Regional focus was not supported, though the need to consider regional differences in pollutant mixtures by some Centers was considered to be useful; c) requiring both large and small Centers within the total program was not supported, though some members noted that a limited number of small focused Centers could provide some benefits as well as some negative impacts to the results that have been historically noted to come from large Centers; and d) having Center structures that support and encourage research partnerships. In addition, the SAB endorsed other activities that will enhance what ever structure that the EPA decides upon for the continued Centers program. Among these are that a) Centers must continue their use of outside, independent expert reviews of their programs to evaluate their progress, and b) Centers should be given the flexibility to change their program content to reflect advice obtained from these groups without jeopardizing their continued funding either as a result of changing research foci or from completion of specific components of the research. Additionally, Centers should continue to integrate programs across Centers and across the research programs conducted within the EPA intramural research programs.

The SAB appreciates the opportunity to review and comment on EPA's plans to continue its Particulate Matter Centers program. We look forward to your response to our comments and we would be pleased to continue to work with EPA as it further develops and implements this important research program.

Sincerely,

Dr. Deborah L. Swackhamer
Chair
Science Advisory Board

Dr. David T. Allen
Chair
SAB Particulate Matter Research Centers Program Advisory Panel

NOTICE

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U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
SAB Particulate Matter (PM) Research Centers Program Advisory Panel
October 1-2, 2008

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Table of Contents

1. INTRODUCTION

` The EPA Science Advisory Board (SAB) was asked by the U. S. Environmental Protection Agency to conduct a review of its Particulate Matter Research Centers Program (US EPA, 2008). EPA was interested in the SAB's advice on: a) the worth of the PM Research Centers past contributions to advancing key particulate matter research in support of EPA's mission; b) the potential for broadening the Centers' programs to have more of a multi-pollutant focus; and c) the strengths and weaknesses of various alternative Center structures that might be used in the future. This advisory provides the SAB's advice to the Administrator as a result of an advisory meeting held on October 1 and 2, 2008 in Washington, DC.

1.1 Background Information:

In 1998, the Congress directed the Environmental Protection Agency to establish as many as five university-based PM research centers as part of the expanded Office of Research and Development (ORD) PM research program. The first PM research centers were funded from 1999 to 2005 with a total program budget of $8 million annually (see the following URL: http://es.epa.gov/ncer/science/pm/centers.html). In the original Request for Applications (RFA), prospective centers were asked to propose an integrated research program on the health effects of PM, including exposure, dosimetry, toxicology and epidemiology. ORD's PM Research Centers program was initially shaped by recommendations from the National Research Council.

In 2002, ORD requested that the Science Advisory Board conduct an interim review of EPA's PM research centers program, the report from which is found at the following URL: http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/$File/ec02008.pdf. This review was instrumental in providing additional guidance to ORD for the second phase of the program (2005–2010).

In 2004, ORD held a second competition for the PM Research Centers program. This RFA asked respondents to address the central theme of "linking health effects to PM sources and components," and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages. From this RFA, five current centers are funded for 2005–2010 with the overall 5-year total program budget at $40 million (see: http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19).

At the request of EPA ORD's National Center for Environmental Research (NCER) the SAB Staff Office formed an expert panel to comment on the Agency's current PM research centers program and to advise EPA concerning the possible structures and strategic direction for the program as ORD contemplates funding a third round of air pollution research centers into the future, *i.e.*, from 2010 to 2015 (see *Federal Register*, 73 FR 5838, of January 31, 2008 which announced the formation of an SAB *ad hoc* panel for this advisory activity and requested public nominations of qualified experts to serve on this panel and the SAB Panel Formation record, US EPA SAB, 2008)).

1.2 EPA Charge to the SAB PM Research Centers Program Advisory Panel

The Agency asked the SAB for advice on the effectiveness of the current Particulate Matter Research Centers Program and suggestions for an improved future Centers Program, and requested that the Panel focus on several charge questions during its review of the PM Research Centers Program:

1.2.1 Overall Charge Questions

Within the context of the current state-of-the-science and the priorities for the EPA Air research program, ORD seeks advice on the possible structures and strategic direction of an Air Research Centers program for 2010 – 2015. Specifically,

1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?

2. What advice does the panel have on how to move to multi-pollutant approach in the PM Centers program?

One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture. What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?

3. What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?

Given the strategic directions discussed above, please comment on various approaches EPA could consider for the *structure* of a future air pollution Centers program. For example, a future Centers program might continue with a common theme for all Centers, or might seek Centers that specialize in different research areas. In addition, some Centers might address a broad research portfolio while others have a more targeted focus. EPA may consider funding fewer Centers in order to maintain appropriate program balance with the individual STAR grants and intramural research programs. EPA is seeking the panel's views on the strengths and weaknesses of different approaches for the structure of the program.

2. RESPONSE TO CHARGE QUESTIONS

2.1 Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?

The PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure, and health impacts. The documentation reviewed by the panel demonstrated that PM Center investigators:

a) are recognized as world leaders in PM health effects research,
b) have improved understanding of the epidemiology and toxicology of particulate matter,
c) have identified mechanisms for PM health effects,
d) have improved our understanding of the populations most susceptible to PM health risks,
e) have identified new micro-environments (e.g., roadways) that lead to ultra-fine particle exposures,
f) have developed new technologies and instruments for PM research,
g) have advanced the understanding of source specific health impacts, and
h) have enhanced the range of expertise available to the EPA in assessing PM health impacts.

The first set of Centers, funded from 1999-2005, produced more than 500 publications, a rate of publications per dollar of funding that is 20% higher than the publication rate per dollar of funding for comparable STAR grants. These publications have been influential, as evidenced by citation rates that are higher than average citation rates in the fields covered by the publications. For example, a 2007 analysis of ORD Air Program publications indicated that about 37% of PM Center papers are in the top 10% in overall citation rate, 6% of PM Center papers are in the top 1%, and 3% are in the top 0.1%.

The assessments of a variety of expert panels have provided additional endorsements of the scientific impact and the relevance of the work of the PM Centers. These have included assessments by BOSC (BOSC, 2005) an SAB panel (US EPA SAB, 2002; the National Research Council of the Nataional Academies (NAS/NRC, 2004) and professional organizations such as the American Heart Association (Brook, 2004), and the American Academy of Pediatrics (AAP, 2004).

The work of the Centers has also been extensively cited in EPA documents supporting policy decisions. The Centers' work contributed to the 2007 PM NAAQS review and the Integrated Science Assessment (ISA) for PM. PM Center work has also influenced policy decisions in regulatory organizations beyond EPA, such as the California law requiring that schools must be at least 500 feet from freeways.

The panel recommends that the EPA continue to use a variety of performance indicators to assess Center performance, and recommends that additional measures be added to those already used in the Center evaluations.

One set of additional measures should characterize the extent to which Center resources are supplemented by other research support. Such supplemental funding from outside of the EPA should not become a requirement of the Centers program, but the extent of supplementation can serve as an indicator of the interest by organizations outside of EPA in the work of the Centers.

A second set of additional measures should broaden the range of indicators that assess Center impacts on the scientific community. Current measures are focused on numbers of journal publications, citations, and students trained. The Centers could also begin to track the impact that program graduates are having on the field after they leave the Centers.

A third set of additional measures should broaden the range of indicators that document the extent to which Center work is used in support of Agency decisions. Current measures focus on documents developed in support of setting National Ambient Air Quality Standards. The Center's work has also been used in Regulatory Impact Assessments, in assessing the costs and benefits of the Clean Air Act (Section 812 analysis), and in other documents developed by EPA in support of its regulatory mission. These uses of the Centers' work should be tracked.

Finally, the panel concluded that the Centers Program produced benefits over those that would be expected in traditional STAR grant mechanisms, involving individual investigators or small teams of investigators focusing on relatively narrow topical areas. These benefits include flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The advantages of Center programs, as compared to traditional STAR grant funding mechanisms, will be expanded on in response to charge question 3. The panel recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed, but also notes that both Centers and individual or small team research initiatives are essential.

2.2 Charge Question 2. <u>What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?</u>

EPA noted that, "*One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture.*" The Agency asked the SAB, "*What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?*"

In reviewing the contributions of the PM Centers program to date, and its potential for the future, the Panel found that the Centers have already begun to make contributions to efforts to address the broader set of pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the next round

of centers. The Panel also found that the next round of Centers could usefully address another important and broad direction: the regional differences in pollutant mixtures, and potential regional differences in health effects.

Enhancing Multipollutant Approaches in the Centers Program: In 2004, the NRC's Committees on *Research Priorities for Airborne Particulate Matter* and *Air Quality Management in the United States* (NAS/NRC, 2004) recommended that the nation's efforts to improve air quality should move from its historical single-pollutant-at-a-time regulatory approach to a multipollutant approach that provides both the science and the regulatory programs to allow for the most cost-effective interventions to reduce exposure and improve public health. Although the setting of multipollutant ambient air quality standards is likely well in the future, the agency is working with states to develop multipollutant air quality management plans, and seeking to move its air quality research program to a multi-pollutant perspective that can increasingly identify the effects of the simultaneous co-exposure to many different pollutants that humans and the ecosystem face.

There are hundreds of compounds in the ambient mix of pollutants; the agency has focused on a subset of these which have been the main targets of the Clean Air Act: the so-called criteria pollutants (especially PM and ozone) as well as some air toxics. The Panel agreed that this subset is useful, but also noted that there are significant "multipollutant" challenges within some pollutant classes, especially PM (with its diverse sources and particle characteristics as well as the variations in gas/particle phase distribution) and ozone and the other photochemical oxidants. Some of the same new methods that would be useful in broader multipollutant approaches across classes of pollutants (i.e. PM, ozone, and air toxics) would also be useful in addressing these significant mixture issues within one class of pollutants.

The Panel agrees that the Agency should find ways to re-direct the PM Centers program so that it is better able to address the broader multi-pollutant context. The development of a more robust set of atmospheric chemistry, exposure, dosimetry, toxicology and epidemiology research methods will be essential to building the evidence necessary to support both nearer term decisions by states and localities about the best integrated intervention strategies, and to laying the foundation for the development of multipollutant ambient standards in the future.

Specifically, the Panel found:

a) Multi-pollutant approaches should be strongly encouraged by EPA in applications for PM Research Centers, with clear encouragement of efforts to develop innovative methods that address multi-pollutant atmospheric transformation, exposure, dosimetry, toxicology, and epidemiology. These new methods could include a range of approaches, from computational toxicology and genomics to enhanced statistical methods for identifying principal components or factors, to novel analytic chemistry.

b) The Panel felt that while the Agency should provide a strong incentive for multipollutant approaches, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches

c) The Panel generally agreed that the Agency's suggestion that organizing its multipollutant efforts around sources could be useful, but cautioned that an over-emphasis only on near-roadway exposures in such efforts could substantially under-represent the importance of other sources and the atmospheric transformation of their emissions that are also significant contributors to exposure.

d) Finally, it will be important to balance the interest in a multipollutant approach with the need to continue answering an increasingly focused set of decision-relevant single pollutant questions that can inform nearer term decisions critical to the Agency's mission to improve public health. This should include science to inform standard setting (e.g. better understanding PM exposure-response and the relative toxicity of PM components). It also should inform implementation (e.g. better tools for source apportionment). But even in these instances, the Centers program should emphasize the need to produce such pollutant-specific evidence as much as possible in a multi-pollutant context to enhance its interpretation.

Addressing Regional Differences: The panel noted the well-known differences in pollutant sources and mixtures in different regions, and emerging evidence of differences in health effects, and found that exploring, characterizing, and understanding these regional differences in exposure and effect should also be a broader direction to be encouraged in a new round of Center awards.

a) As with multi-pollutant approaches the Panel felt that systematic approaches to addressing regional differences should be strongly encouraged by EPA, with a clear indication that such efforts will enhance the applicant's chances of being selected. Here too, the Panel felt that while the Agency should provide a strong incentive for addressing regional differences, it should not mandate specific approaches, but rely on the skills and innovation of the research community to propose new approaches.

b) The Panel further found that addressing these regional differences could take two forms:

   i First, individual centers that could demonstrate a systematic approach to exploring and understanding differences in exposure and health in two or more regions should be encouraged; and

   ii Second, once centers are selected, and to the extent that they represent geographical differences in their location and focus, EPA should foster enhanced collaboration and coordination among the relevant centers on regional differences.

2.3 Charge Question 3. <u>What strengths and weaknesses does the panel see in different options for a future Centers Research Program?</u>

The PM Centers panel recognizes the successes of the PM Centers program over the last 8 years as discussed in Change question 1. Since the Program is successful, some members questioned the need to make major changes, suggesting "if it's not broken, do not fix it." However, as the Agency redirects the Centers toward more multi-pollutant approaches and examination of regional differences, some structural and operational changes should be considered. The panel considered both specific structural changes for the Centers program under consideration by the Agency, and broader structural and operational features of the Centers. These are described, by topic, in paragraphs a) through g).

a) The agency asked the panel to consider whether all Center applicants should address the same research topics.

The panel agreed that the PM Centers should be asked to choose from among a desribed set of priority research topics, as has been the case in the past. The RFA should describe the range of desired research and let the applicants decide on the exact research topics and approaches. It is then up to the Agency to select an appropriate research portfolio, based on quality, relevancy, and the extent to which the applicants propose research topics which complement other Intramural and Extramural research programs.

b) The agency asked the panel to consider whether all Center applicants should have a regional focus.

The consensus of the Panel was that the requirement of funding Centers based on their regional locations would not be a structurally beneficial alteration to the Program, despite some benefits in supporting regulatory decisions, such as providing closer links to regional, state, and local officials and facilitating identification of regional issues.

There are important regional differences in atmospheric contaminants and health outcomes that need to be studied and understood. The development of regional centers may help delineate these differences; however, other scientific approaches may be scientifically better and more cost effective. For example, as noted above in response to Question 2, individual centers could explore and understand differences in exposure and health in two or more regions and EPA could foster enhanced collaboration and coordination among the centers on regional differences.

c) The agency asked the panel to consider whether individual Centers should continue to be funded at their current level or whether a larger number of Centers, funded at a smaller level would be more effective.

There are advantages and disadvantages to having only Centers funded at or near the current level (large Centers) or a mixture of large and small Centers. The funding of both large and small Centers was favored by a minority of the panel. The main concern

of most of the panel was that funding limited or small Centers would diminish the impact of the program and would diminish some of the advantages of large Centers cited in response to Charge question 1.

The funding of small Centers would allow Research Centers that are not as comprehensive or developed as the large Centers to be funded and develop their research program. The funding of small Centers also provides the agency the opportunity to select research programs that may fill a very specific research need. While the funding of small centers has advantages the loss of the large Center effect and the transfer of funding from large to small Centers was not supported by the majority of the Panel members.

d) The panel encourages the Centers to develop core laboratories that can be shared and to pursue supplementary funding

Other potential structural elements that the Agency is encouraged to entertain is the potential use of Core laboratories shared among the Centers; and encouraging the Centers to identify complementary research programs that can supplement Center activities. The Panel also recommends that the EPA search to find research partners that may help fund this Program. NIEHS, NIHHL, NIGMS, ALA, AHA, ATS would be just some of the federal and non federal programs that may help fund this research. Other Centers programs of the EPA have been successful in developing outside EPA funding to share costs of the program. The focus of funding from other agencies should be to augment Center research, rather than as a replacement for EPA funding.

e) The panel encourages the Centers to continue their tradition of ongoing evaluation and scientific flexibility

The Centers must continue to have a process for periodic evaluation of research programs.The Centers should have the flexibility to alter specific projects within the Center that have been completed, or that are unproductive or that need to move in new directions. This should be done in consultation with the Center oversight committees and the Agency.

f) The panel encourages the Centers to continue their tradition of internal integration and integration with the agency.

The Centers have a strong tradition of integration of science, data, and methodology, allowing rapid progress of the state of the art in science and methods within individual Centers and within the PM Centers program. Integration with internal agency programs should be encouraged to the extent practicable.

g) The panel encourages the Centers to continue their tradition of strong External Advisory Panels

The Centers and RFA should continue their use of external advisory Panels. Some panel members felt that it may be helpful if the Centers consider community involvement in the Panels, particularly if the Center has a regional focus, however there was not a panel consensus on this recommendation.

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