

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

March 21, 2006

EPA-CASAC-LTR-06-002

Honorable Stephen L. Johnson Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter

Dear Administrator Johnson:

EPA's Clean Air Scientific Advisory Committee (CASAC), supplemented by subject-matter-expert panelists — collectively referred to as the CASAC Particulate Matter (PM) Review Panel ("PM Panel") — held a public teleconference meeting on February 3, 2006 to consider whether to provide the Agency with additional advice and recommendations concerning EPA's proposed revisions to the PM National Ambient Air Quality Standards (NAAQS).

The PM Panel agrees that this letter adequately represents their views. The chartered CASAC — whose seven members are also members of the PM Panel — fully endorses the PM Panel's letter and hereby forwards it to you as the CASAC's consensus letter on this subject. The current Clean Air Scientific Advisory Committee roster is found in Appendix A of this letter, and the PM Panel roster is attached as Appendix B.

This meeting continued the PM Panel's review and recommendations on the Agency's revision to PM NAAQS. The most recent reports to you on this topic — *i.e.*, the PM Panel's final report from its peer-review of the 2nd draft PM Staff Paper (EPA-SAB-CASAC-05-007, dated June 6, 2005); and the CASAC's final report (EPA-SAB-CASAC-05-012, dated September 15, 2005) concerning the PM Panel's August 11, 2005 teleconference to review EPA Staff recommendations concerning a potential thoracic coarse PM standard in the final PM Staff Paper — are found at URLs: http://www.epa.gov/sab/pdf/casac-05-007.pdf and http://www.epa.gov/sab/pdf/sab-casac-05-012.pdf, respectively.

The CASAC requests reconsideration of the proposed ruling for the level of the annual PM_{2.5} NAAQS so that the standard is set within the range previously recommended by the PM Panel, *i.e.*, 13 to 14 μ g/m³. The CASAC also recommends that the proposed 24-hour PM_{10-2.5}

primary standard be accompanied by a national monitoring program for PM_{10-2.5} in both urban and rural areas to aid in informing future health and welfare effects studies on rural dusts. Moreover, the CASAC strongly recommends expansion of our knowledge of the toxicity of PM_{10-2.5} dusts rather than exempting specific industries (*e.g.*, mining, agriculture). Finally, the CASAC requests that the sub-daily secondary standard to protect visibility, as recommended both in the PM Staff Paper and by the CASAC, be favorably reconsidered. The scientific rationale for the CASAC's recommendations is given in the remainder of this letter.

1. Background

The CASAC, comprised of seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (CAA or "Act") (42 U.S.C. § 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act. The PM Panel is comprised of the seven members of the chartered (statutory) Clean Air Scientific Advisory Committee, supplemented by fifteen technical experts.

EPA announced its proposal to revise the NAAQS for particulate matter on December 20, 2005. This proposal was published in the *Federal Register* in a January 17, 2006 (71 FR 2620-2708) notice entitled, "National Ambient Air Quality Standards for Particulate Matter; Proposed Rule." As announced in that notice, the Agency will accept comments on the proposed rule for PM NAAQS for 90 days after its publication in the *Federal Register*.

2. CASAC Recommendations Concerning the Agency's Proposal to Revise the PM NAAQS

In August 2005, the CASAC, through its PM Panel, completed an extensive review of the PM air quality criteria document and the PM staff paper, making its recommendations to the Agency based on the current science. The CASAC acknowledged and was pleased that the EPA has chosen to accept its advice on some revisions of the PM NAAQS. However, the PM Panel noted that some of the scientific recommendations were not accepted. The CASAC recognizes that the EPA Administrator must include policy judgments as well as scientific information in making his decisions. That is one reason that the CASAC's recommendations for levels of the NAAQS are given in ranges, rather than as a single level. The value that the Administrator chooses within that range is clearly a policy judgment. The CASAC and the PM Panel have held in-depth discussions and deliberations, as described in previous reports, on the scientific data underpinning the basis for the recommended ranges. To underscore its previous recommendation, the CASAC would like to reiterate and expand the scientific rationale behind its advice, to better inform the Administrator on the scientific basis of its recommendations.

<u>Proposed 24-hour PM_{2.5} standard level</u>: Generally, members of the PM Panel were pleased to see that the recommended revision of the 24-hour PM_{2.5} level of the standard was within the range of that recommended by most members of the PM Panel. The PM Panel recognizes that, as a policy judgment, the high end of the suggested range was chosen.

<u>Proposed annual PM_{2.5} standard level</u>: For this NAAQS level, the Agency has chosen to propose going outside the range of the CASAC-recommended levels and to retain the annual standard level at its current level of 15 μ g/m³. Our report to you dated June 6, 2005 stated,

"There was a consensus among the [PM] Panel members in agreement with the EPA staff recommendations that focused on decreasing PM_{2.5} concentrations through lowering of the 24-hour PM standard, but the [PM] Panel did not endorse the option of keeping the annual standard at its present level. It was appreciated that some cities have relatively high annual PM concentrations, but without much variation in concentrations from day-to-day. Such cities would only rarely exceed a 24-hour PM_{2.5} standard, even if set at levels below the current standard. This observation indicates the desirability of lowering the level of the annual PM_{2.5} standard as well.

Of the options presented by EPA staff for lowering the level of the PM standard, based on the above considerations and the predicted reductions in health impacts derived from the risk analyses, most [PM] Panel members favored the option of setting a 24-hour PM_{2.5} NAAQS at concentrations in the range of 35 to 30 μ g/m³ with the 98th percentile form, in concert with an annual NAAQS in the range of 14 to 13 μ g/m³."

The CASAC would like to reiterate and elaborate on the scientific basis for the PM Panel's earlier recommendation, as follows:

First, the Agency's risk assessment indicating reduced health risks at annual $PM_{2.5}$ levels below the current standard was a key component in the PM Panel's recommendation to lower the current annual level. While the risk assessment is subject to uncertainties, most of the PM Panel found EPA's risk assessment to be of sufficient quality to inform its recommendations. The authors of the Agency's risk assessment followed CASAC's advice in conducting extensive sensitivity analyses and in revising the threshold assumptions as published in the final PM Staff Paper. The risk analyses indicated that the uncertainties would increase rapidly below an annual level of $13~\mu g/m^3$ — and that was the basis for the PM Panel's recommendation of $13~\mu g/m^3$ as the lower bound for the annual $PM_{2.5}$ standard level.

In our June 6, 2005 report, the PM Panel noted that "some cities have relatively high annual PM $_{2.5}$ concentrations, but without much variation in concentrations from day-to-day." Dependence on a lower daily PM $_{2.5}$ concentration limit alone cannot be relied on to provide protection against the adverse effects of higher annual average concentrations. The changes suggested in the 24-hour standard will have significant impact when done "in concert" with a change in the annual standard. The effect of changing the short-term (98th percentile) and long-term standard levels in concert can be seen in Figures 5-1 and 5-2 of the Agency's staff paper. The cities of St. Louis and Detroit are examples of cities where the estimated reduction in PM $_{2.5}$ -related short-term and long-term mortality risk with a daily standard of 35 μ g/m³ would be enhanced by a concerted reduction in the annual standard below the current level of 15 μ g/m³.

While the risk analysis is the primary means of determining the effects on risk of changes in the 24-hour and annual $PM_{2.5}$ standards in concert, there is evidence that effects of long-term $PM_{2.5}$ concentrations occur at or below the current annual standard level of 15 $\mu g/m^3$. Studies described in the PM Staff Paper indicate that short-term effects of $PM_{2.5}$ persist in cities with

annual PM_{2.5} concentrations below the current standard. In a Canadian study (Burnett *et al.*, 2000; and Burnett and Goldberg, 2003), significant associations with total and cardiovascular mortality were present at a long-term mean PM_{2.5} concentration of 13.3 μ g/m³. There were also positive findings in studies in Phoenix, AZ (Mar *et al.*, 1999, 2003) and in Santa Clara County, CA (Lipsett *et al.*, 1997) in which long-term mean concentrations of PM_{2.5} were approximately 13 μ g/m³.

In summary, the epidemiologic evidence, supported by emerging mechanistic understanding, indicates adverse effects of $PM_{2.5}$ at current annual average levels below 15 $\mu g/m^3$. The PM Panel realized the uncertainties involved in setting an appropriate, health-protective level for the annual standard, but noted that the uncertainties would increase rapidly below the level of 13 $\mu g/m^3$. That is the basis for the PM Panel recommendation of a level at 13-14 $\mu g/m^3$.

Therefore, the CASAC requests reconsideration of the proposed ruling for the level of the annual PM_{2.5} NAAQS so that the standard is set within the range previously recommended by the PM Panel, i.e., 13 to $14 \mu g/m^3$.

<u>Proposed 24-hour PM_{10-2.5} Standards</u>: The PM Panel was pleased to see that the indicator for coarse thoracic particles of concern to public health took into account some of the various approaches that the PM Panel identified for consideration. However, the PM Panel is concerned that some of the advice provided may have been misunderstood, as follows:

- 1. <u>Monitoring</u>: Our report of September 15, 2005 indicated that it was essential to monitor coarse thoracic particle concentrations in both rural and urban areas. As stated therein, "It is essential to have data collected on the wide range of both urban and rural areas in order to determine whether or not the proposed UPM_{10-2.5} standard should be modified at the time of future reviews."
- 2. Source of toxic components in coarse thoracic particles: The preamble to the proposed rule on PM NAAQS cites "specific initial advice from CASAC (Henderson, 2005)," which was "most [PM] Panel members concurred that the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles." However, that same report also underscored the associated "need for monitoring thoracic coarse particle levels [in rural areas] and for population-based health-effects studies in those rural areas where it is feasible to conduct such studies." The CASAC neither foresaw nor endorsed a standard that specifically exempts all agricultural and mining sources, and offers no protection against episodes of urban-industrial PM_{10-2.5} in areas of populations less than 100,000.
- 3. <u>Secondary PM_{10-2.5} Standards</u>: As stated in the CASAC's report of September 15, 2005, the CASAC recommends that a secondary PM_{10-2.5} standard be set at the same level as the primary PM_{10-2.5} standard to protect against the various irritant, soiling and nuisance welfare or environmental effects of coarse particles. Since these effects are not uniquely related to urban sources or receptors, the standard should not be limited to urban areas.

Accordingly, the CASAC recommends that the proposed 24-hour $PM_{10-2.5}$ primary standard be accompanied by monitoring of particles in both urban and rural areas to aid in informing future health effects studies on rural dusts. Moreover, the CASAC strongly recommends expansion of our knowledge of the toxicity of rural dusts rather than exempting specific industries (e.g., mining, agriculture). Serious consideration should also be given to a secondary $PM_{10-2.5}$ at a level similar to the proposed primary standard, but without the "urban" geographical constraint.

Proposed Secondary PM_{2.5} Standard to Protect Visibility: To protect visibility, the EPA staff paper, with concurrence of most CASAC members, recommended a sub-daily standard for PM_{2.5} with a level in the 20 to 30 μ g/m³ range for a four- to eight-hour (4-8 hr) midday time period with a 92nd to 98th percentile form. The upper end of this range (25-30 μ g/m³ and a 92% to 95% form) was considered to be "lenient" in terms of protecting visibility, permitting a relatively high number of days with relatively poor visual air quality. It was suggested as a starting point for a national secondary standard given the uncertainties in both the current science of what is adverse to the public and in the mechanics of setting and operating a new sub-daily standard to protect visibility.

The proposed rule recommended relying on the proposed 24-hour primary standard of 35 $\mu g/m^3$ as a surrogate for visibility protection, noting through analysis that a percentage of counties with monitors (and the corresponding percentages of populations) not likely to meet the sub-daily secondary standard with a lenient level and form is comparable to those not likely to meet a 24-hour primary standard set at the proposed 35 $\mu g/m^3$ level. EPA's proposal to revise the NAAQS for PM also cited limitations in the science and in the available hourly air quality data required for a sub-daily standard.

CASAC members note three cautions to the Agency's proposed visibility standard, which was outside the range recommended in the EPA staff paper and by most of the PM Panel:

- 1. As both the Staff Paper and the preamble to the proposed rule on PM NAAQS note, the PM_{2.5} mass measurement is a better indicator of visibility impairment during daylight hours when humidities are low. Moreover, the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during daylight hours. Using the 24-hour primary standard as a proxy introduces error and uncertainty in protecting visibility Sub-daily secondary standards are used elsewhere (*e.g.*, a three-hour secondary standard for SO₂ and an eight-hour secondary standard for ozone), and should be the focus for visibility.
- 2. CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM measurements in various aspects of its monitoring strategy (e.g., Hopke, March 1, 2002; Henderson, April 20, 2005). The PM Panel notes that expanded deployment of continuous PM_{2.5} monitors is consistent with setting a sub-daily standard to protect visibility, especially given that compliance time frames for secondary standards are less rigid than for primary standards.
- 3. The cited comparability between percentages of counties not likely to meet a lenient subdaily secondary standard and the proposed 24-hour primary standard is a numerical coincidence, and is not indicative of any fundamental relationship between visibility and

health. Visual air quality is substantially impaired at $PM_{2.5}$ concentrations of 35 $\mu g/m^3$. However, peak short-term concentrations during daylight hours can be substantially higher than 24-hour average values, and the Agency is specifically seeking comments on whether the 24-hour primary standard should be set at an even higher level. It is not reasonable to have the visibility standard tied to the health standard, which may change in ways that make it even less appropriate for visibility concerns.

Thus, the CASAC requests that the sub-daily secondary standard to protect visibility, as recommended both in the PM Staff Paper and by most of the PM Panel, be favorably reconsidered.

Consideration of More Recent Scientific Information: The Agency has agreed to consider more recent publications if they are critical to the setting of new standards. Whether a new study is critical to the setting of new standards is difficult to determine. The CASAC is concerned that the newer literature suggested by either CASAC or by the general public will not have had a chance to undergo thorough EPA staff and CASAC review in a public setting. Such an approach would set a bad precedent for future reviews and weaken the role of the independent scientific review process. The PM Panel arrived at its recommendations based on the literature presented in the PM Air Quality Criteria Document and in the PM Staff Paper (publications through 2004). Scientific literature published since that time appears to support the findings of the PM Panel, but is not needed to support the original conclusions of the PM Panel. Individual members of the PM Panel, in response to the Administrator's request, have suggested new articles to consider, which are listed in Appendix C. These articles have not been reviewed either by EPA staff or by the CASAC in a public setting.

Views of PM Panel Members Not in Agreement with Majority Opinion: Finally, it should be noted that two of the 22 members of the PM Panel do not agree with the majority opinion of the PM Panel. These two PM Panel members expressed the view that the PM Staff Paper provided an adequate scientific basis for the EPA Administrator to propose an annual PM_{2.5} standard from within the range of 12 to 15 μ g/m³ and a 24 hour PM_{2.5} standard from within the range of 30 to 40 μ g/m³. It was their opinion that the choice of specific numerical levels from within the ranges was a policy decision. They also expressed the view that the Administrator, as well as individual scientists, might have different preferences from among the various policy options. Thus, these two PM Panel members felt that the choices made by the Administrator in the Proposed PM Rule are scientifically acceptable. One of these two PM Panel members also felt that the Administrator's decision to propose the use of the primary 24-hour PM_{2.5} NAAQS as a secondary standard for visibility was an appropriate policy decision. He expressed the view that the science reviewed by and commented on by the PM Panel should inform the policy decision; however, the policy decision as to the level of visibility to accept is a responsibility of the Administrator outside the purview of the PM Panel.

Concluding Remarks: In conclusion, the members of the CASAC PM Review Panel have carefully reviewed this letter, and all seven members of the statutory CASAC and a substantial majority of PM Panel members are in agreement that this letter, with the exception of the preceding paragraph immediately above, represents their views as expressed during the PM Panel's February 3, 2006 teleconference and subsequent e-mail correspondence to me.

The CASAC is pleased to provide scientific advice to the Administrator concerning the proposed new standards for airborne particulate matter. We recognize that the setting of a NAAQS goes beyond the scientific data base into the realm of pubic policy. However, the efforts of the Agency's scientific staff as well as the CASAC in providing a sound scientific basis must, fundamentally, be the foundation of these standard-setting decisions. The members of the CASAC hope that we can continue to work with EPA both to provide the best scientific advice available and to aid the Agency in protecting the public health and the environment in an effective and efficient manner.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair Clean Air Scientific Advisory Committee

Appendix A – Roster of the Clean Air Scientific Advisory Committee

Appendix B – Roster of the CASAC Particulate Matter Review Panel

Appendix C – Newer Literature Suggested by Individual PM Panel Members

Appendix A – Roster of the Clean Air Scientific Advisory Committee

U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office Clean Air Scientific Advisory Committee (CASAC)

CHAIR

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

MEMBERS

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Dr. James D. Crapo, Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

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Appendix B – Roster of the CASAC Particulate Matter Review Panel

U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office Clean Air Scientific Advisory Committee (CASAC) CASAC Particulate Matter Review Panel

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Dr. Petros Koutrakis, Professor of Environmental Science, Environmental Health, School of Public Health, Harvard University (HSPH), Boston, MA

Dr. Allan Legge, President, Biosphere Solutions, Calgary, Alberta

Dr. Paul J. Lioy, Associate Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ - Robert Wood Johnson Medical School, NJ

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

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Mr. Ronald White, Research Scientist, Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. Warren H. White, Visiting Professor, Crocker Nuclear Laboratory, University of California - Davis, Davis, CA

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^{*} Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

Appendix C – Newer Literature Suggested by Individual PM Panel Members

- Sun *et al.* (2005): Long-term air pollution exposure and acceleration of atherosclerosis and vascular inflammation in an animal model, *JAMA* 294, 3003-3010. Suggested by Dr. Morton Lippmann. Cardiovascular effects were observed in animals chronically-exposed to PM_{2.5}: The animal inhalation studies reported in Sun *et al.* (2005) used an atherosclerosis-prone mouse model in demonstrating that exposure of these mice to concentrated PM_{2.5} ambient air particles for six months resulted in altered vasomotor tone, induced vascular inflammation and acceleration of atherosclerosis.
- Laden *et al.* (2006): Reduction in fine particulate air pollution and mortality: extended follow-up of the Harvard Six Cities Study, *Am J. Respir. Crit. Care Med.* 173:667-672. Suggested by Dr. Frank Speizer. Reduction in annual ambient PM_{2.5} levels lead to a reduction in human health effects: The paper of reports that cardiovascular and lung cancer mortality were each positively-associated with ambient PM_{2.5} concentrations and that a reduction in PM_{2.5} concentrations was associated with reduced mortality risk. The study was an extended follow-up of the Harvard Six Cities Study and found improved overall mortality was associated with decreased mean PM_{2.5} levels between Period 1 (1980-1985) and Period 2 (1990-1998).
- **Dominici** *et al.* (2006): Fine Particles and Hospital Admission for Cardiovascular and Respiratory Diseases: Results for 204 US Counties, 1999-2002, *JAMA* 295(10):1127-1134. Suggested by Mr. Ron White. This study involving 204 urban counties and 11.5 million Medicare enrollees was just published in *JAMA* in March 2006, and found statistically-significant relationships between a 10 μ g/m³ increase in PM_{2.5} and hospitalization for cerebrovascular, peripheral, and ischemic heart diseases, heart rhythm, heart failure, chronic obstructive pulmonary disease, and respiratory infection. No association was found between PM_{2.5} levels and hospital admissions for injury, which served as the control. The average of county mean PM_{2.5} concentrations for the 1999-2002 study period was 13.4 μ g/m³.
- Bayer-Oglesby et al. (2005): Decline of ambient air pollution levels and improved respiratory health in Swiss children, Environ. Health Perspec. 113, 1632-1637. Suggested by Dr. Rogene Henderson. This paper reported reductions in morbidity in children in nine cities in Switzerland during a time of reduced PM_{10} (which would include $PM_{2.5}$). Various indicators of respiratory problems were compared for Period 1 (1993) and Period 2 (1997-2000). Beneficial effects from the reduction in particles were observed, with no threshold. Significant reductions in morbidity indicators were associated with reductions in particles even below 15 μ g/m³.
- **Pope** *et al.* (2004): Cardiovascular mortality and long-term exposure to particulate air pollution: Epidemiological evidence of general pathophysiological pathways of disease. *Circulation* 109:71-77. Suggested by Dr. Morton Lippmann. The report on the ACS cohort indicated that long-term PM_{2.5} exposures were most strongly associated with mortality attributable to ischemic heart disease, dysrhythmias, heart failure and cardiac arrest.

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- Krewski *et al.* (2005): Mortality and long-term exposure to ambient air pollution: ongoing analyses based on the American Cancer Society cohort. *J. Toxicol. Environ. Health* 68:1093-1109. Suggested by Dr. Frank Speizer. Ongoing analyses based on the ACS cohort in many cities across the country reported robust associations between ambient fine particulate air pollution and elevated risks of cardiopulmonary and lung cancer mortality
- **Kunzli et al.** (2005): Ambient air pollution and atherosclerosis in Los Angeles. *Environ. Health Perspect.* 113:201-206. Suggested by Dr. Frank Speizer. In an additional study in humans an association was found between estimated long-term exposure to PM_{2.5} and carotid artery intimal medial layer thickening.
- **Jerrett** *et al.*(**2005**): Spatial analysis of air pollution and mortality in Los Angeles. *Epidemiology* 16:727-736. Suggested by Dr. Frank Speizer. Health risk estimates were larger using smaller spatial scale exposure estimates. The association between air pollution and mortality using small-area exposure measures within Los Angeles indicated relative risk ratios for mortality resulting from ischemic heart disease and lung cancer in the range of 1.24-1.6.
- Enstrom (2005): Fine particulate air pollution and total mortality among elderly Californians, 1973-2002. *Inhalation Toxicology* 17:803-816. Suggested by Dr. Roger McClellan. The epidemiologic results of the study do not support a current relationship between fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly before 1983.
- **Moolgavkar** (2005): A review and critique of the EPA's rationale for a fine particle standard. *Regulatory Toxicology & Pharmacology* 42:123-144. Suggested by Dr. George Wolff. The author of the review concludes that a particle mass standard is not defensible on the basis of a causal association between ambient particle mass and adverse effects on human health.

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.