EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

April 13, 2006

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

Dear Mr. Johnson:

We recently concluded review of the Agency's Notice of Proposed Rulemaking (NPRM) on the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). The purpose of this letter is to follow up on several issues that we discussed at length with your staff during our review: (1) key steps that need to be taken to complete the rulemaking, and (2) the longer-term need for innovative scientific research to address the gaps in public health knowledge about fine PM.

The PM Rulemaking

The Agency staff devoted much time and energy to complete the Regulatory Impact Analysis (RIA) in mid-January to ensure its publication in conjunction with the NPRM. The Clean Air Act (CAA) requires the Administrator to set health-based standards requisite to protect public health with an "adequate margin of safety" without considering cost. Nevertheless, the Environmental Protection Agency (EPA) conducted such an analysis to provide the public and Congress with an assessment of the projected consequences -- benefits and costs -- of the rulemaking.

EPA has stated that the draft RIA issued with the NPRM will require substantial additional work prior to publication of the final rule. For example, EPA plans to develop further the underlying emissions inventory database and its database of available control measures and costs. EPA also expects to provide national benefit and cost estimates for an illustrative set of approaches to meeting the proposed fine PM standard (and the alternative standards considered in the analysis). We have also discussed with EPA the importance of including within the RIA a sensitivity analysis that explores alternatives to the assumption that all particles are equally toxic. In its recent 2005 Thematic Clean Air Strategy, the European Commission included a benefit-cost analysis that built on some of the models and approaches pioneered by your Agency. However, this analysis also included sensitivity analyses that depart from the assumption that "all particles are equally toxic" by presenting an alternative set of benefit estimates based on the assumption that the gaseous precursors to fine particles (especially sulfates and nitrates) are less toxic than primary combustion particles.[1]

[1] AEA Technology Environment, *CAFE Cost-Benefit Analysis: Baseline Analysis 2000 to 2020* (Didcot, United Kingdom: AEAT, 2005), 54. Available at: http://europa.eu.int/comm/environment/air/cafe/activities/pdf/cba_baseline_results2000_2020.pdf.

We think that it is also important that the final RIA: (1) convey the uncertainty in the exposure-response model using, among other techniques, expert elicitation; and (2) provide a robust treatment of the economic consequences of meeting these standards. These objectives are consistent with previous advice from the National Academies that, "EPA should begin to move the assessment of uncertainties from its ancillary analyses into its primary analyses by conducting probabilistic, multiple-source uncertainty analyses. This shift will require specification of probability distributions for major sources of uncertainty. These distributions should be based on available data and expert judgment."[2]

Regarding the NPRM, we have several specific concerns about the way the Agency is applying the underlying epidemiological studies in this rulemaking. First, we are concerned that the Agency's risk assessment and resulting cost-benefit analysis for the proposed fine PM standard relies too heavily on a series of analyses that are sensitive to plausible changes in model specification (Pope et al., 1995; Krewski et al. 2000; Pope et al., 2002). The preamble at 71 FR 2652 outlines an alternative view regarding this sensitivity to changes in model specification. In light of the degree of sensitivity of the relative risk estimates based on the American Cancer Society (ACS) cohort to model specification and the importance that the Agency places on these estimates, we believe that it is important to provide a more complete characterization of the uncertainty in our understanding of the nature and magnitude of the premature mortality effect. For the longer-term, the Agency would do well to conduct additional analysis of the ACS data set. In this regard, it would be helpful if the Agency would work with the relevant authorities to make sure that the data used by Pope et al. (2002) are publicly available for analysis. In the short-term, the Agency should present a broader set of alternative models in the RIA.

Second, given that the Agency has concluded that adverse health effects (including both cardiovascular and/or respiratory effects) are related to exposure to fine PM, we think any assessment of the effect of coarse fraction PM should control for exposure for fine PM (as well as control for potential confounding with other co-pollutants).[3] The key epidemiology results serving as the basis for the proposed coarse fraction standards primarily rely on one-pollutant models – i.e., coarse fraction PM is the only variable used in the statistical model reflecting exposure to air pollution. As outlined in the preamble at 71 FR 2671, most of the studies also report a positive, statistically significant association between cardiovascular and respiratory health effects and other co-pollutants, particularly fine PM. Indeed, the association for fine PM is more consistent and robust across these studies than the association reported for coarse fraction PM. In the short-term, the Agency will need to decide in the final rulemaking whether the evidence associated with the health effects of coarse fraction PM are sufficiently robust to justify a coarse fraction PM NAAQS. As outlined below, long-term progress on this issue will depend upon the Agency's ability to carry out a research strategy that can distinguish the causal mechanisms associated with the various constituents of PM and the associated co-pollutants.

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[2] National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (Washington, DC: National Academies Press, 2002), 14.

[3] See also *Health Aspects of Air Pollution – answers to follow-up questions from CAFE* (Bonn, Germany: World Health Organization, 2004), 43. Available at http://www.euro.who.int/document/E82790.pdf. See also the preamble at 71 FR 2672.

Long-term Research Concerns

In the past, the Office of Information and Regulatory Affairs (OIRA) has expressed concern about whether the Agency was giving adequate priority to research aimed at addressing: (1) the potential confounding of PM health effects with other air pollutants; (2) the attribution of PM health effects to specific constituents (e.g., sulfates versus nitrates versus organic and elemental carbon, and metals), and (3) the quantitative relationship between exposure to different particles and various health effects.[4] OIRA applauds the progress the Agency has made in many areas of PM research[5], including the recent request for research proposals by the Health Effects Institute. However, we remain concerned that progress has not been made in certain areas of PM research that directly influence EPA's ability to set and effectively implement the NAAQS. In reviewing this NPRM, OIRA notes that the Agency is making some of the same simplifying assumptions and relying heavily on some of the same data sources that EPA has been using over the last decade.

Although the current scientific evidence allows us to conclude that there are potentially serious health effects from PM, without more specific data we will not be able to determine the extent to which further reductions in ambient PM levels or specific management strategies designed to meet more stringent standards will lead to reductions in these health effects. The implications of the confounding associated with the effects of fine and coarse fractions may become clear through analysis of effects differentiated by species. This information would help policymakers compare the relative merits of adopting: a more stringent fine PM standard (undifferentiated by type), a coarse fraction PM standard, standards for specific constituents (e.g., carbon) of PM, and/or more stringent standards for the gaseous pollutants (e.g., SO_2, NO_2, and CO). Indeed, the most recent NAS review of the "Research Priorities for Airborne Particulate Matter" highlighted the importance of "developing a systematic program to assess the toxicity of different components of the PM mixture, planning and implementing new studies of the effects of long-term exposure, improving the relevance of toxicological approaches, enhancing the nation's air quality monitoring system, and ultimately moving beyond PM to a multipollutant approach."[6]

We respectfully reiterate our request that the Agency give priority to the development of analytic tools and databases necessary to inform decision makers about potential differences in the toxicity of different particles. Moreover, we urge the Agency to aggressively pursue, as one of its highest scientific priorities, a science-based understanding of which particles are the most

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[4] On December 4, 2001, the OIRA Administrator wrote Administrator Whitman concerning the remaining gaps in scientific knowledge about the public health benefits of reducing human exposure to fine particulate matter. See http://www.reginfo.gov/public/prompt/epa_pm_research_prompt120401.html and http://www.reginfo.gov/public/prompt/prompt_pm.pdf.

[5] Environmental Protection Agency, *Particulate Matter Research Program: Five Years of Progress* (Washington, DC: EPA, 2004). Available at http://www.epa.gov/pmresearch/pm_research_accomplishments.

[6] National Research Council, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (Washington, DC: National Academies Press, 2004), 151.

toxic for public health. As the NAS concluded, "A failure to invest in advancing the understanding of the effects of PM and air pollution on health risk would result ... [in] limiting the nation's ability to make evidence-based health policy and air quality regulatory choices in the future".[7]

Sincerely,

Donald R. Arbuckle
Acting Administrator and
Deputy Administrator
Office of Information
and Regulatory Affairs

cc: William L. Wehrum, EPA
George Gray, EPA

[7] NRC 2004, 168.