Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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April 17, 2008

The Honorable Tom Davis
Ranking Minority Member
Committee on Oversight and Government Reform
U.S. House of Representatives
B-350B Rayburn House Office Building
Washington, DC 20515

Dear Mr. Davis:

Thank you for your letter of April 16, 2008, in which you request an investigation of the role of President Clinton in the establishment of ozone standards established by the U.S. Environmental Protection Agency (EPA) in 1997. You have requested that the Committee seek records from the National Archives relating to this issue.

As you may recall, these standards have already been exhaustively examined by Congress. In the 105th Congress, there were approximately thirty days of hearings in at least ten Committees on this topic.[1] EPA Administrator Carol Browner personally testified over a dozen times regarding the standards.[2]

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[1] Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (Field Hearing held in Oklahoma City, OK) (February 5, 1997) (S. Rpt. 105-0050, pt.1); Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (February 12, 1997) (S. Rpt. 105-0050, pt.1); Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (March 3, 1997) (S. Rpt. 105-0050, pt.1); House Subcommittee on Energy and Environment, Committee on Science, *Science Behind the Environmental Protection Agency's (EPA's) Proposed Revisions to the National Ambient Air Quality Standards for Ozone and Particulate Matter, Part 1*, 105th Cong. (March 12, 1997); Senate Subcommittee on VA, HUD, and Independent Agencies, Committee on Appropriations, *Appropriations Hearing on EPA*, 105th Cong (April 8, 1997); House Subcommittee on Health and Environment and House Subcommittee on Oversight and Investigations, Committee on Commerce, *Review of EPA's Proposed Ozone and Particulate Matter NAAQS Revisions*, 105th Cong. (April 10, 1997); House Subcommittee on VA,HUD, Independent Agencies Appropriations, Committee on Appropriations, *Appropriations Hearing on EPA*, 105th Cong. (April 15, 1997); House Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs, Committee on Government Reform and Oversight, *EPA's Proposed Standards for Particulate Matter and Ozone: Is EPA Above the Law?*, 105th Cong. (April 16,

Our own Committee conducted an investigation of the matter. Subcommittee Chairman David McIntosh sent letters of inquiry to numerous agencies, including the Office of

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1997); House Subcommittee on Health and Environment and House Subcommittee on Oversight and Investigations, Committee on Commerce *Review of EPA's Proposed Ozone and Particulate Matter NAAQS Revisions*, 105th Cong. (April 17, 1997); House Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs, Committee on Government Reform and Oversight, *EPA's Proposed Standards for Particulate Matter and Ozone: Is EPA Above the Law?*, 105th Cong. (April 17, 1997); House Subcommittee on Forestry, Resource Conservation, and Research, Committee on Agriculture, *Oversight of Air Quality Issues Relating to the Agricultural Industry*, 105th Cong. (April 23, 1997); House Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs, Committee on Government Reform and Oversight, *EPA's Proposed Standards for Particulate Matter and Ozone: Is EPA Above the Law?*, 105th Cong. (April 23, 1997); Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (April 24, 1997) (S. Rpt. 105-0050, pt.2); Senate Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety and Senate Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (April 29, 1997) (S.Rpt. 105-0050, pt.2); House Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations, Committee on Commerce, *Review of EPA's Ozone and Particulate Matter NAAQS Revisions, Part 2*, 105th Cong. (May 1, 1997); House Subcommittee on Energy and Environment, Committee on Science, *Science Behind the Environmental Protection Agency's (EPA's) Proposed Revisions to the National Ambient Air Quality Standards for Ozone and Particulate Matter, Part 2*, 105th Cong. (May 7, 1997); House Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations, Committee on Commerce, *Review of EPA's Proposed Ozone and Particulate Matter NAAQS Revisions, Part 2*, 105th Cong. (May 8, 1997); House Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations, Committee on Commerce, *Review of EPA's Ozone and Particulate Matter NAAQS Revisions, Part 2*, 105th Cong. (May 15, 1997); House Subcommittee on Energy and Environment, Committee on Science, *Science Behind the Environmental Protection Agency's (EPA) Proposed Revisions to the National Ambient Air Quality Standards for Ozone and Particulate Matter, Part 3*, 105th Cong. (May 21, 1997); Senate Committee on Agriculture, Nutrition, and Forestry, *EPA's Clean Air Regulations and Agriculture*, 105th Cong. (July 22, 1997) (S. Rpt. 105-0590); Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Committee on Environment and Public Works, *Clean Air Act: Ozone and Particulate Matter Standards*, 105th Cong. (July 24, 1997) (S. Rpt. 105-0050, pt.2); House Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, *Oversight – EPA's Rulemakings on the National Ambient Air Quality Standard for Particulate Matter and Ozone*, 105th Cong. (July 29, 1997); House Committee on Agriculture, *EPA's National Ambient Air Quality Standards For Ozone and PM 2.5*, 105th Cong. (September 16, 1997); Senate Subcommittee on Manufacturing and Competitiveness, Committee on Commerce, Science, and Transportation, *Impact of EPA's New Air Quality Standards on U.S. Small Manufacturing Jobs and Competitiveness*, 105th Cong. (September 24, 1997) (S. Rpt. 105-0834); House Committee on Resources, *Oversight Hearing on Issues Surrounding Use of Fire as a Management Tool and Its Risks and Benefits as they Relate to the Health of the National Forests, and the EPA's National Ambient Air Quality Standards*, 105th Cong. (September 30, 1997); House Subcommittee on Health and Environment and Subcommittee on Oversight and Investigations, Committee on Commerce, *Implementation of the Clean Air Act National Ambient Air Quality Standards Revisions for Ozone and Particulate Matter*, 105th Cong. (October 1, 1997); Senate Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety, Senate Committee on Environment and Public Works, *Ozone and Particulate Matter Research Act of 1997*, 105th Cong. (October 22, 1997) (S. Rpt. 105-0355).

[2] American Association for the Advancement of Science, Debate over Air Quality Standards Intensifies (June 1997) (online at http://www.aaas.org/spp/cstc/pne/pubs/stc/bulletin/articles/6-97/caa2.htm).

Management and Budget (OMB), EPA, and the White House Council of Economic Advisors.[3] The scope of these requests was expansive, and the Subcommittee received a voluminous record.

Mr. McIntosh requested that OMB "produce all records related to [Office of Information and Regulatory Affairs] OIRA's review of the proposed rules."[4] In response to this and other congressional requests, OMB produced thousands of pages of documents, including internal White House communications, and apparently withheld only "two memoranda to the President from senior advisors within the Executive Office of the President."[5] Mr. McIntosh's subcommittee also interviewed OMB and EPA officials involved in the rulemaking, Clean Air Scientific Advisory Committee (CASAC) scientists, state and local authorities, and economic and policy analysts.[6] In response to requests from Mr. McIntosh, EPA sent the Subcommittee over 30 pages of written responses to questions and provided the Subcommittee with boxes of responsive documents. For your convenience, I am enclosing letters from both EPA and OMB that respond to Chairman McIntosh's inquiries.

This record demonstrates that Congress, especially our Committee, spared no effort in conducting oversight over the Clinton rulemaking. It also shows that the Clinton Administration was extraordinarily responsive to our Committee's extensive demands for interviews and documents.

Your April 16, 2008, letter also expresses concern that EPA Administrator Carol Browner may have disregarded the opinion of EPA's Clean Air Scientific Advisory Committee, citing a *Wall Street Journal* editorial that quoted Dr. George Wolff, the General Motors scientist and former chair of CASAC. In fact, Dr. Wolff wrote EPA Administrator Browner:

> It was the consensus of the Panel that EPA's selection of ozone as the surrogate for controlling photochemical oxidants is correct. It was also the consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard. The Panel was in unanimous agreement that the present 1-hour standard

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[3] House Committee on Government Reform and Oversight, *Interim Report of the Activities of the House Committee on Government Reform and Oversight*, 105th Congress (March 1998).

[4] Letter from Rep. David M. McIntosh, Chairman, National Economic Growth, Natural Resources, and Regulatory Affairs, Committee on Government Reform and Oversight, to Sally Katzen, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (Jan. 17, 1996).

[5] Letter from Sally Katzen, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, to Rep. Tom Bliley, Chairman, House Committee on Commerce (Mar. 7, 1997).

[6] House Committee on Government Reform and Oversight, Interim Report of the Activities of the House Committee on Government Reform and Oversight, 105th Congress (March 1998).

> be eliminated and replaced with an 8-hour standard.... It was also the consensus of the Panel that the form of the 8-hr standard be more robust than the present 1-hour standard.[7]

Dr. Wolff also stated: "it was the consensus of the Panel that the ranges of concentrations and allowable exceedences proposed by the Agency were appropriate."[8] I have enclosed a copy of Dr. Wolff's letter for your convenience.

For these reasons, I do not believe we need to expand this investigation into actions that were taken eleven years ago and already thoroughly examined by Congress.

Finally, I appreciate your request for a witness from OMB. Earlier this week, I invited the Director of OMB or his designee to appear before the Committee in order to answer any questions you may have.

I hope this response addresses your concerns.

Sincerely,

Henry A. Waxman
Chairman

Enclosures

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[7] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to the Honorable Carol M. Browner, Administrator, U.S. EPA (Nov. 30, 1995).

[8] Letter from Dr. George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to the Honorable Carol M. Browner, Administrator, U.S. EPA (Nov. 30, 1995).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 28 1997

OFFICE OF
AIR AND RADIATION

Honorable David M. McIntosh
Chairman
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
Committee on Government Reform and Oversight
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is in response to your letter of January 24, 1997 to Administrator Browner. In your letter, you requested that the Environmental Protection Agency (EPA) provide certain information in response to your inquiries concerning the proposed national ambient air quality standards (NAAQS) for particulate matter (PM) and ozone (O_3). The EPA's response is presented below in the format you requested: a restatement of your question, followed by the Agency's answer.

1. Regulatory Flexibility Act. The Subcommittee is concerned that EPA has not properly evaluated or considered the impacts of the proposed rules on family-run businesses and other small entities in its decision making. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act, requires you to prepare an initial regulatory flexibility analysis of the proposed rules' effects on small businesses and on other small entities. The EPA's certification that the proposed NAAQS will not have a significant economic impact on a substantial number of small entities and its refusal to comply with other requirements of the RFA is insupportable.

(a) Please state whether EPA will conduct an initial regulatory flexibility analysis and publish a new set of proposed rules that complies with the RFA.

For the proposed NAAQS, EPA analyzed the potential impacts on small entities of implementing the NAAQS as part of the Regulatory Impact Analyses it prepared for the proposals.

However, as described below, an initial regulatory flexibility analysis (IRFA) requires analysis that cannot be done at this stage of the NAAQS process. An IRFA is to look at how the rule could be designed to include special provisions for small entities. NAAQS are not susceptible to this type of analysis because they do not establish requirements applicable to small entities. Instead, the NAAQS establish performance standards that States are primarily responsible for meeting. Decisions regarding what entities must comply with what regulations in what timeframes are thus not made until later.

The Regulatory Flexibility Act (RFA) requires that an agency prepare an IRFA for a rule unless the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities" (RFA sections 603 and 605(b)). For rules like the NAAQS, the RFA, the Small Business Regulatory Enforcement Fairness Act (SBREFA) and federal caselaw all make clear that agencies may properly certify that the rule will not have a significant impact on a substantial number of small entities. For the reasons stated in the NAAQS proposals and further explained below, the Agency properly made such a certification and therefore did not conduct an IRFA for the NAAQS.

The RFA provisions governing the content of regulatory flexibility analyses illustrate that the point of those analyses is to determine how a rule will impact the small entities that must comply with the rule and how the agency issuing the rule can design the rule to minimize that impact. Specifically, sections 603 and 604 require that regulatory flexibility analyses identify the types and estimate the numbers of small entities "to which the proposed rule will apply" (sections 603(b)(3) and 604(a)(3)). Similarly, they require a description of the "projected reporting, record keeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement" (sections 603(b)(4) and 604(a)(4)). At the heart of the analyses is the requirement that agencies identify and consider "significant regulatory alternatives" that would "minimize any significant economic impact of the proposed rule on small entities" (sections 603(c) and 604(a)(5)). Among the types of alternatives agencies are to consider are the establishment of different "compliance or reporting requirements or timetables" for small entities and

exempting small entities "from coverage of the rule, or any part" of the rule (section 603(c)(1) and (4)).

The findings and purpose section of the RFA confirms that regulatory flexibility analyses are to identify and address the impacts of rules on small entities subject to the rule. "It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations and governmental jurisdictions subject to regulation" (PL 96-354, section 2(b)).

The SBREFA reinforces the conclusion that the RFA is aimed at rules that establish requirements that small entities must meet. Section 212(a) of SBREFA requires that an agency issue a "small entity compliance guide" for "each rule . . . for which an agency is required to prepare a final regulatory flexibility analysis under section 604" of the RFA. The guide is "to assist small entities in complying with the rule" by "explain[ing] the actions a small entity is required to take to comply" with the rule (SBREFA section 212(a)). Obviously, it makes no sense to prepare a small entity compliance guide for a rule that does not apply to small entities, so SBREFA stands as further confirmation that regulatory flexibility analyses are intended to address rules that establish requirements small entities must meet.

The Federal courts also take this view. The United States Court of Appeals for the D.C. Circuit recently affirmed an earlier decision holding that the impacts of concern under the RFA are the impacts of a rule on the small entities subject to the requirements of the rule. United Distribution Companies v. FERC, 88 F.3d 1105, 1170 (D.C. Cir. 1996) ("[N]o [regulatory flexibility] analysis is necessary when an agency determines 'that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule,'" citing Mid-Tex Elec. Co-op v. FERC, 773 F.2d 327, 342 (D.C. Cir. 1985) (emphasis added by United Distribution court)).

As you know, new or revised NAAQS are based on the air quality criteria issued under section 108 of the Clean Air Act, and set at levels sufficient to protect the public health and

welfare from the adverse effects of the pollutant of concern. Once a NAAQS is set or revised, the States are primarily responsible for ensuring attainment and maintenance of it. Under title I of the Act, States develop State implementation plans (SIPs) containing control measures as needed to attain and maintain a level of air quality that complies with the NAAQS.

Under this framework, the proposed NAAQS, if adopted, would not establish any requirements applicable to small entities. Instead, the standards would establish levels of air quality that States would achieve by adopting plans containing specific control measures for that purpose. State regulations implementing a NAAQS may establish requirements applicable to small entities, but the NAAQS itself does not. NAAQS rulemakings are thus not susceptible to regulatory flexibility analysis as prescribed by the amended RFA. They establish no requirements applicable to small entities, and thus afford no opportunity for the Agency to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rules. Moreover, since NAAQS are not applicable to small entities, there would be no point in issuing small entity compliance guides under SBREFA for them.

For these reasons, EPA appropriately certified that the O_3 and PM NAAQS rulemaking actions will not, if promulgated, have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The Agency thus will not conduct an initial regulatory flexibility analysis for the proposed NAAQS.

As noted above, the Agency did conduct analyses of the possible impact on small entities of potential State approaches to implementing any revised NAAQS. These analyses provide as much insight into the potential small entity impacts of implementing revised NAAQS as can be provided at this point in the NAAQS process. The Agency has also taken steps to ensure that small entities' voices are heard and considered in the NAAQS rulemakings and in the development of potential strategies for implementing any revised NAAQS. With Jere Glover, Chief Counsel for Advocacy of the Small Business Administration (SBA), we have convened a panel modeled on the RFA panel process to solicit and

convey small entities' concerns with the proposed NAAQS revisions. The first meeting in this process was held January 7, 1997 with representatives of SBA and the Office of Management and Budget (OMB) attending; the second meeting is scheduled for February 28, 1997. We plan to complete panel reports based on these meetings and to consider the panel reports in making final decisions about revising the NAAQS.

The Agency also intends to conduct one or more additional panels in conjunction with our efforts to develop materials for State implementation, the precise elements of which are in flux. However, regardless of the ultimate composition of the implementation materials, we intend to analyze and address the possible impact on small entities of potential State approaches to implementing any revised NAAQS and to employ panel procedures before issuing any proposed guidance or rules concerning State implementation of revised NAAQS. These steps will include: assessing to the extent possible any potential impact on small entities of NAAQS implementation by the States; conducting small-entity outreach on those issues; preparing an interagency panel report on small entities' concerns and recommendations with respect to implementation issues; and completing an analysis of any potential small entity impacts in light of the panel report. The Agency will then consider whether to make any changes in light of the report. Together with the aforementioned panel on the NAAQS themselves, these procedures will ensure that we identify and carefully consider small entities' concerns with the potential effects of implementing revised NAAQS in a timely way.

(b) Please produce all records relating to the requirements or applicability of the RFA to the proposed rules, including any legal advice or opinions from EPA's Office of General Counsel or any other officer or employee in the executive branch.

In response to your request, the Agency offices involved in addressing the issue of the NAAQS proposals and the RFA were asked to search for all responsive records. Included in the search request were the Office of the Administrator, the Office of Air and Radiation (OAR) (particularly the Office of Air Quality Planning and Standards and Office of Policy Analysis and Review within OAR), the Office of General Counsel (OGC) (particularly the Air and Radiation, Cross-Cutting Issues and the Water Divisions within OGC), the Regulatory Management Division

within the Office of Policy Planning and Evaluation, and the Office of Water. The Agency officials and staff within those offices were given copies of your request, including the instructions pertaining to document requests, and asked to search their files, including their computer files.

We did not ask that the Offices search their back-up computer tapes because it was unlikely such a search would yield documents in addition to those being produced. The records we are producing include many computer messages from the spring and summer of last year when the Agency was addressing the issue of the NAAQS proposals and the RFA. Most EPA offices' back-up tapes do not extend back more than two or three months. As you know, searches of back-up tapes are very costly, and we believe incurring such a cost is not warranted in this case.

The searches conducted by Agency officials and staff yielded the enclosed records, which are summarized in the attached inventory. We wish to note, however, that many of the records are deliberative in nature or contain material subject to the attorney-client privilege. In providing you with these records, we are not waiving the Agency's ability to invoke exemption 5 under the Freedom of Information Act (FOIA) for deliberative or attorney-client documents or the attorney-client privilege in general. In addition, some of the records are personal (as opposed to Agency) records, and thus would not be subject to FOIA or discovery in a civil suit against the Agency. We therefore request that you preserve their confidentiality by refraining from providing privileged or personal records or copies of those records, or from otherwise communicating the contents of those records, to persons other than those with a need to know as part of this oversight review. We have enclosed with this letter a list of the records that indicates which records are personal or covered by the attorney-client privilege, the deliberative process privilege or both. Given the particular sensitivity of the attorney-client privileged documents, we have also marked them "privileged."

As you requested, we have sequentially numbered the records responsive to your request, indicated which records are responsive to which question, and submitted an inventory, since the records together are more than 100 pages. We have also indicated the source of each record, which we interpret to mean

the EPA employee who had the record at the time of the request. If there is any additional information you would like with respect to these records, please contact Ms. Anderson at the number noted above.

(c) With regard to any oral advice you or any senior EPA official received on the requirements or applicability of the RFA, please identify the parties to each conversation and the substance of any advice.

At several meetings with senior Agency officials (Assistant Administrator or above), the issue of the applicability of the RFA to the NAAQS was discussed. The meetings occurred on July 2 and 16, 1996, with General Counsel Jonathan Cannon, and on July 17, 1996, with Deputy Administrator Fred Hansen, Assistant Administrator Robert Perciasepe and Mr. Cannon and myself. One or more of the meetings were attended by the following senior Agency managers: Associate General Counsels Lisa Friedman, Susan Lepow, and Alan Eckert, Senior Counsel to the Administrator Margaret Schneider, Small Business Advocacy Chairperson Tom Kelly, Deputy Director of the Office of Air Quality Planning and Standards Lydia Wegman, and Deputy Director of the Office of Science and Technology James Hanlen. Unscheduled, informal conversations also took place at which the issue was discussed, but we do not have a reliable means of determining when those conversations occurred.

The oral advice provided to senior officials in these meetings and conversations is reflected in, or was consistent with, the Agency and personal records described above. Apart from these records, we do not have a reliable means of reconstructing what was said in the meetings and conversations, which took place over six months ago. As indicated by the list of the senior officials and managers participating in these discussions, many people were involved, and it is highly unlikely that we could accurately recount now all of the oral advice that was given then. In light of the records we are providing, we also question the usefulness of inherently less reliable post hoc accounts. More fundamentally, whatever advice Agency officials received, the basis for the decision Agency officials made is set forth in the Federal Register notices proposing the revised NAAQS, and it is on that basis that the Agency's decision should be and will be judged.

(d) Please explain why EPA changed its position on the need to conduct regulatory flexibility analyses from that taken in other air quality standard-setting rulemakings, such as the sulfur dioxide NAAQS reproposal, and state who made the decision to reverse EPA's position.

The Agency's basic approach to analyzing the potential small entity impacts of implementing NAAQS has not changed over time. In 1987, EPA established the PM_{10} NAAQS. In that rulemaking, the Agency noted that NAAQS do not have a direct impact on small entities, 52 FR 24654 (July 1, 1987), and that the potential effect of proposed revisions could not be determined until States decided how to implement them, 55 FR 10422 (Mar. 20, 1984). Unable to answer the specific questions prescribed by the RFA, EPA instead conducted the type of analysis it conducted for the current NAAQS proposals; i.e., a general analysis of the possible impacts on small entities of potential State strategies for implementing the NAAQS. As here, the Agency ultimately certified that the PM_{10} NAAQS would not have a significant economic impact on a substantial number of small entities.

For the more recent decisions to retain the SO_2 NAAQS, EPA similarly noted that analyzing the NAAQS' impact on small entities would necessarily be speculative, given States' role in implementing the standards. 53 FR 14938 (April 26, 1988) (proposal). Again, the Agency performed the same kinds of analyses as described above regarding the possible effects of implementing the proposed regulatory alternatives, 59 FR 58974-75 (Nov. 15, 1994)(reproposal), and ultimately certified that its decisions on the SO_2 NAAQS would not have a significant economic impact on a substantial number of small entities. 61 FR 25577 (May 22, 1996) (primary standards); 58 FR 21358 (April 21, 1993) (secondary standard).

For some past NAAQS actions, EPA did label its analysis of potential small entity impacts a "regulatory flexibility analysis," even though all of the analyses, as in this case, were general in nature and based on hypothetical State control strategies. For the reasons discussed above, EPA has determined that the kinds of analyses it is possible to conduct on the NAAQS do not meet the terms of the RFA because of the inapplicability of NAAQS to small entities. The Agency has thus decided that it

is inappropriate to label such analyses as regulatory flexibility analyses.

2. The Subcommittee also is concerned with EPA's refusal to properly evaluate and consider overall costs and other economic impacts of the proposed NAAQS in its decision making. Based on the latest scientific knowledge, EPA's own Clean Air Scientific Advisory Committee (CASAC) has concluded that it is not possible to determine at what level to set the air quality standards for PM and ozone in order to protect public health with an adequate margin of safety. The panel has concluded that there is no standard that will eliminate all risk, that only small health differences separate the current ozone standard and the most stringent proposed alternative, and that there are significant uncertainties surrounding the relationship between fine particulates and adverse health effects. Because there are no bright scientific lines, EPA has recognized that setting these standards entails inherent policy judgments.

(a) <u>Unfunded Mandates Reform Act</u>

(i) Given that the Agency has the discretion not to change the existing air quality standards, and that setting any new PM or ozone standard involves a policy judgment, please explain in detail why EPA maintains that the provisions of the Clean Air Act (Act) prohibit it from considering the effects of the proposed changes on State, local, tribal governments and the private sector and from selecting the least costly, most cost-effective, and least burdensome alternative that achieves the objectives of the Act.

The Act requires a periodic (every 5 years) review of both the scientific criteria and the air quality standards themselves. As you indicate, the Act does not automatically require a revision of the standards following such reviews. However, an important question in the review of the standards is whether, in light of the latest scientific and technical information contained in the updated criteria document, the standards continue to protect public health with an adequate margin of safety. As discussed in greater detail in the responses to questions 6 ad 8, the scientific evidence evaluated in the criteria documents and staff papers for PM and ozone indicate that large numbers of people experience adverse health effects at levels below the current standards. The consensus of the

CASAC Panel was that these documents provide an adequate scientific basis for making regulatory decisions on the standards.

Under section 109 of the Act, NAAQS levels are to be based solely on the effects of air pollutants on public health and welfare, and costs are not to be considered in setting them. This principle has been strongly affirmed in a number of court decisions since 1980. Natural Resources Defense Council v. Administrator, 902 F.2d 962, 972-73 (D.C. Cir. 1990)(PM NAAQS), vacated, in part, dismissed, 921 F.2d 326 (D.C. Cir.), certs. dismissed, 498 U.S. 1075, cert. denied, 498 U.S. 1082 (1991); Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1157-59 (D.C. Cir.)(en banc)(sec. 112 standards for vinyl chloride); American Petroleum Institute v. Costle, 665 F.2d 1176, 1185-86 (D.C. Cir. 1981)(ozone NAAQS), cert. denied, 455 U.S. 1034 (1982); Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1148-51 (D.C. Cir.)(lead NAAQS), cert. denied, 449 U.S. 1042 (1980). It is the basis for EPA's conclusion that certain requirements of the Unfunded Mandates Reform Act (UMRA) are inapplicable to NAAQS decisions.

The UMRA section 202 requirement to prepare a written statement assessing costs and benefits of a proposed or final rule does not apply to rules, such as the NAAQS, for which the Agency is prohibited from taking such assessments into account. Section 202 requires the assessment "unless otherwise prohibited by law." The Conference Report for UMRA clarifies the meaning of this phrase, stating that section 202 "does not require the preparation of any estimate or analysis if the Agency is prohibited by law from considering the estimate or analysis in adopting the rule," as noted on page 3 of Sally Katzen's March 31, 1995, Memorandum for the Heads of Executive Departments and Agencies regarding Guidance for Implementing Title II of S. 1 (see Enclosure A). The section 205 requirement "to select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule" or to explain why such alternative was not selected also does not apply, because section 205 applies only when a written statement is required under section 202.

Even though these UMRA requirements do not apply to the NAAQS, EPA believes it has the authority to help the States

fashion implementation strategies that minimize the costs of meeting NAAQS, and that are sensitive to impacts on State and local governments. EPA has therefore undertaken extensive efforts to address any State and local issues in State implementation of the proposed NAAQS. These efforts include the following:

- The EPA is holding meetings with State and local officials on the potential impacts of implemention of the standards. The EPA is also analyzing the potential impact on State and local government as they work with EPA to implement the standards. The EPA's ongoing reanalysis of the RIA's will contain information on these estimates and also analyze the administrative costs to State and local governments, such as the cost of developing State implementation plans.

- The EPA has created a subcommittee -- comprised of State and local government officials, among other stakeholders -- under the Federal Advisory Committee Act (FACA) to develop the actual framework State and local governments may use to implement a revised O_3 or PM standard.

- Once that subcommittee has developed the implementation strategy, EPA will again revise the RIA to reflect that information.

- In the meantime, EPA has already significantly increased the grant money it provides to State and local governments under the Clean Air Act. The EPA included $2.75 million in its 1997 budget to help States establish a PM 2.5 monitoring network. The Clinton Administration has requested an additional $10.9 million for that purpose in its 1998 budget.

- Furthermore, over the past several months EPA has held numerous meetings with State environment commissioners and State and local air pollution control agency officials to estimate the costs of implementing a revised O_3 or PM standard. In its 1999 budget request EPA intends to reprogram grant funds to help defray additional costs associated with any revised standards. As the Agency develops its 1999 budget, we will assess the need for additional grant funds to further support the States' work.

Specific areas potentially needing additional grant funds include: developing emission inventories; analyzing air quality data; preparing area designations; drafting and adopting needed rules; developing State implementation plans; and implementing those State plans.

In summary, we believe that EPA's efforts constitute a significant and substantial effort to address unfunded mandates issues, even though UMRA is not formally applicable to the NAAQS proposals.

(ii) Please produce all records relating to the requirements or applicability of the Unfunded Mandates Reform Act to the proposed rules, including any legal advice or opinions from EPA's Office of General Counsel or any other officer or employee in the executive branch. In addition, please document the Agency's efforts to consult with representatives of State, local, and tribal governments to inform them about the effects of the proposed rules and related regulatory actions and to respond to their concerns.

In response to your request to produce all records relating to the requirements on applicability of UMRA, we have produced the records indicated by the inventory as responsive to this question.

As discussed above, EPA has established a Subcommittee of the Clean Air Act Advisory Committee (CAAAC) that includes representatives of State, local, and tribal governments for the purpose of providing advice and recommendations on how to develop more cost-effective and common sense implementation programs. As part of this process, EPA will respond to concerns raised when developing new implementation programs. In addition, during the development of the air quality surveillance requirements for both $PM_{2.5}$ and PM_{10}, found in 40 CFR part 58, EPA consulted extensively with State and local officials engaged in air quality monitoring. To address concerns raised, appropriate revisions were made prior to proposal. Comments received on the proposal from State and local officials, as well as others, will be carefully considered before final action is taken.

In addition, during November and December, 1996, EPA held briefings on this topic for the National Governors Association,

the U.S. Conference of Mayors, and the Council of State Governments. The Agency also sent the following letters informing outside parties about the proposed rules:

- On November 26, 1996, Administrator Browner wrote to all Governors to inform them that she would soon be signing a proposed rule to change the existing NAAQS for PM and ozone.

- On January 8, 1997, Administrator Browner and each Regional Administrator wrote to the Mayors of cities potentially affected by the proposed NAAQS rules to inform them of the health basis of the proposals, and to inform them that EPA would be conducting public hearings in Boston, Massachusetts, Salt Lake City, Utah and Chicago, Illinois.

- On January 17, 1997. Administrator Browner and each Regional Administrator wrote to the chairs of environmental committees in the State Legislatures to inform them of the health basis of the proposals.

- On January 31, 1997, Administrator Browner replied to a letter written to her on December 19, 1996 from the chairs of seven national associations requesting a 60 day extension of the public comment period for the NAAQS proposal. Administrator Browner informed the chairs of the associations that EPA was going to request such an extension from the court.

- On February 13, 1997, Administrator Browner wrote again to the writers of the December 19, 1997 letter informing them that we had received a 21 day extension of the public comment period from the court.

(b) <u>Executive Order 12866</u>

(i) Executive Order 12866 requires the Agency to "assess the costs and benefits of available regulatory alternatives, including the alternative of not regulating" or, in this case, not issuing new standards. Please provide all records indicating the extent to which EPA has reviewed, evaluated, and accounted for the following health benefits in determining the need to propose new or revised PM and ozone standards at this time: the progress that already has been made under the Act in

reducing concentrations of both ozone and particulate matter, and the projected health benefits attributable to attaining the current NAAQS and complying with other Act programs.

The EPA has considered in its analysis of the new PM and O_3 NAAQS both the progress that has been made under the Act in reducing concentrations of both O_3 and PM and projected health benefits attributable to attaining the current NAAQS and complying with other clean air programs. As detailed in the RIA's (see Enclosures B and C), the analytical baseline used for both the O_3 and PM analyses reflects the emission reductions and air quality improvements achieved through all relevant mandatory control measures contained in the Act, such as Title I O_3 nonattainment requirements for nitrogen oxides (NO_x) and volatile organic compounds (VOC's), Title II mobile source controls, and the sulfur dioxide controls under the Acid Rain Program among others as of the forecast year 2007.

Further, the additional benefits and costs of attainment of the current standards were assessed prior to analysis of the new standards. Thus, the costs and benefits EPA has reported for the proposed standards are both incremental to those associated with implementation of other CAA requirements and attainment of the current standards.

Based on our analyses, the benefits of partial attainment of the new PM and O_3 standards in 2007 incremental to implementation of the Clean Air Act Amendments and partial attainment of the current standards are estimated to be an additional $58 to $120 billion (1990$), while corresponding incremental control costs are estimated to be an additional $7 to $9 billion (1990$).

(ii) Given the policy judgments involved, explain in detail why it would be inconsistent with the Act to take into account all relevant information, including economic factors, in determining whether the proposed new or revised PM and ozone standards would be more effective in achieving healthier air than the current standards.

As indicated in the response to question 2(a)(i) above, the Act and related case law preclude the consideration of costs in setting NAAQS.

(iii) In these rulemakings, where the requirements and objectives of the Act can be satisfied by any one of two or more alternatives, is there any reason why Congress should not expect the Agency to choose the most cost-effective alternative that protects public health and the environment? If not, why should Congress allow an agency to choose the least cost-effective alternative that might never be fully implemented?

This question assumes that the objectives of the Act can be satisfied by two or more alternatives. This is not the case. Although the staff paper identified "ranges" of standard levels for consideration by the Administrator, neither the staff nor CASAC ever indicated that all levels within the ranges would necessarily satisfy the statutory requirements. The Administrator has explained in detail her rationale for concluding, based on the available scientific information, that the PM and O_3 NAAQS should be revised to protect public health and welfare from the adverse effects of these pollutants, and that the revised standards she proposed would achieve the objectives of the Act. Recognizing that others may reach different judgments with respect to both the available scientific information and the most appropriate response, the Administrator has solicited broad public comment on alternative views that would result in more or less protective standards than those proposed. Ultimately, based on the available scientific evidence, and taking into account public comment on that evidence, the Administrator will have to determine the degree of protection that is necessary to protect public health, with an adequate margin of safety, and welfare from the adverse effects of these pollutants. Once this objective of the Act is met, EPA will help States fashion implementation strategies that minimize costs of meeting the NAAQS.

3. <u>Congressional Review Act</u>. Although it would be premature for Congress to consider resolutions of disapproval under the Congressional Review Act (CRA) to overturn any new NAAQS that EPA might ultimately issue, the Subcommittee is troubled that you are telling the public that the CRA would not apply to the final rules. The final NAAQS rules will be covered under the CRA, because each will be an Agency statement "of general or particular applicability and future effect."

(a) Although Congress could act on a joint resolution of disapproval under the CRA even if EPA refused to submit a covered

rule, please state for the record whether or not you intend to submit the final rules and supporting materials for congressional review in accordance with the CRA.

Contrary to what you may have heard, the Administrator and senior Agency officials have publicly stated that the final NAAQS rules will be submitted to Congress as required by the Congressional Review Act of 1996 (CRA) (subtitle E of the Small Business Regulatory Enforcement Fairness Act). Indeed, Administrator Browner so stated in response to a question she received at the November press conference announcing the NAAQS proposals. The Agency intends to submit the final NAAQS rules for congressional review at the time they are submitted to the Federal Register.

(b) Please set forth the legal basis for EPA's position that the CRA does not apply to NAAQS rulemakings. In this regard, produce all records relating to the applicability of the CRA to the final PM and ozone NAAQS rules, including any legal advice or opinions from EPA's General Counsel's Office or any other officer or employee in the executive branch.

As explained above and as indicated by the record listed in the inventory under this question, EPA believes the CRA **does** apply to the final NAAQS rules.

(c) Please state whether you believe the Interim Implementation Policy on the proposed ozone and PM NAAQS would be a covered rule under the CRA.

As you know, EPA published the draft Interim Implementation Policy (IIP) for public comment at the same time it proposed the NAAQS revisions. When the Agency makes final decisions about the policy, it will determine whether the contents of the final policy meet the definition of "rule" under the CRA.

4. Please explain in detail why EPA did not perform full cost analyses for its PM and ozone proposals. Provide the Subcommittee with your best estimates of the expected costs of full compliance with each of the proposed standards. In either case, if you believe that implementation of all known regulatory measures would still not achieve the proposed standards in all regions or cities, then provide your best estimates of the additional costs for making further improvements in air quality

that fall short of achieving the standard.

The RIA analyses employed a reasonable set of available control measures for reducing ambient concentrations of PM and O_3. However, the EPA air quality and cost models predict that some areas with significant air pollution problems may not attain the new standards by 2007, the period selected for the RIA analyses. This is not surprising since the Clean Air Act Amendments of 1990 envisioned attainment dates for some areas at 2007 and beyond even for the current standards. This incomplete attainment situation may be due in part to uncertainties in the models used as well as the lack of consideration of a more recent and extensive set of control measures. Some cost-effective measures - - for example, phase in of cleaner new-vehicles as older, more polluting models are retired - - may require longer than 10 years for the full benefits to be recognized. Additional control strategies necessary to achieve full attainment of the proposed standards are likely to be identified in the future through control technology improvements over the next decade and through innovative and cost-effective strategies developed by EPA's Subcommittee of the CAAAC.

The EPA has developed rough estimates for full attainment benefits and costs but did not provide them in the RIA documents given the large uncertainties involved. In response to your question, however, we provide the following approximation. The benefits of fully attaining the two new standards are estimated to be an additional $70 to $147 billion incremental to full attainment of the current O_3 and PM standards. Using simplified calculation techniques which EPA believes may overstate the costs, full attainment costs for both pollutants are estimated to range from $20 to $29 billion.

5. Your PM Regulatory Impact Analysis cites a case analysis of Philadelphia and Denver that estimated the cost and air quality impact of cutoffs greater than $1 billion/$\mu g/m^3$. According to the RIA, "Results of this analysis indicated that higher cutoffs achieve minimal air quality improvements at an unreasonably high cost."

(a) Doesn't this study reveal that the cost of full attainment is much larger than your partial analysis would suggest? If not, please explain in detail why not.

The Philadelphia and Denver sensitivity analyses in and of themselves have no implications for the total costs of controls in these cities, both of which may well attain the proposed fine particle standards under currently mandated programs at no incremental cost over baseline. The cost cut-offs developed in these analyses have, however, been used in providing the very uncertain estimates of the total costs of attaining the standards for the projection year of 2007. As noted in response to question 4 above, these rough estimates are clearly larger than those for partial attainment. Also, as noted above, EPA believes this approach to estimating such costs will significantly overstate the costs that would actually be incurred in a full attainment scenario. It is important to remember that the statute would provide for additional time beyond 2007. Moreover, this rough approach does not permit assessment of more innovative and cost-effective control/prevention polices and measures that are likely to be developed under the FACA process and future technological innovations. In any event, even a comparison with these rough estimates of full attainment costs, estimated benefits of full implementation exceed costs for all $PM_{2.5}$ standards alternatives analyzed.

(b) Please produce the data used in this case study, and explain in detail why EPA has not discussed and addressed the implications of this analysis with respect to the achievability of your PM proposal for the country at large.

You will find a copy of the two EPA contractor reports which contain the data you requested on the implications of the $1 billion cost per microgram reduced cutoff used in the PM RIA cost analysis (Enclosures D and E). It is important to recognize that this cost cutoff is unique to the cost modeling approach used in the PM RIA and can be understood only in the context of PM control cost optimization across broad, multi-State regions. Based upon the case studies conducted for Denver and Philadelphia cited in the PM Regulatory Impact Analysis (RIA), this cutoff was used in the cost model to eliminate cost-ineffective control measures within a region due to one of two reasons: 1) control measures that may be extremely costly due to their large geographic distance from a violating county and potentially small contribution to ambient PM concentrations in a violating county; 2) local control measures that may be extremely costly given a

small contribution to ambient PM concentrations within the violating county either because the sources are located downwind of the violating area or the sources represent a small proportion of emissions contributing to ambient PM concentrations within the violating county. Control measures on sources falling into the above two categories likely would not be considered in reality given their cost-ineffectiveness.

As indicated in the PM RIA and in responses to questions 4 and 5(a) above, it is likely that more cost-effective measures can be identified either now, through development of innovative and cost-effective control strategies by EPA's Subcommittee of the CAAAC, or in the future, through innovation in control technologies. It is expected, therefore, that the costs of further progress towards attainment would be reduced. This kind of progress has occurred in many areas over the last 10 years -- for example, the development of selective catalytic reduction (SCR) enabled sources to get more emission reductions at less cost; better catalysts enable automobiles to meet tighter standards; power plant scrubbers became much more effective, and more cost-effective; and diesel fuels and gasoline have been made much cleaner.

6. Given that the Act does not require the Agency to revise the current NAAQS, and that most members of your scientific panel advised against lowering the ozone standard because it would provide only marginal public health benefits, why does EPA prefer the proposed ozone standard revision in which the costs of the rule would outweigh the benefits?

The Act requires a review at least once every five years of both the scientific criteria and the air quality standards themselves. As you indicate, the Act does not automatically require a revision of the standards following such reviews. However, an important question in the review of the standards is whether, in light of the latest scientific and technical information contained in the updated criteria document, the standards continue to protect public health with an adequate margin of safety. Taken as a whole, the scientific evidence evaluated in the EPA's criteria document and summarized in the staff paper indicate that, at levels below the current standard, O_3 affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. The

consensus of the CASAC Panel was that these documents provide an adequate scientific basis for making regulatory decisions on the standard.

The key studies identified in this review showed that some moderately exercising individuals exposed for 6 to 8 hours at O_3 levels as low as 0.08 ppm experienced such health effects as decreased lung function, respiratory symptoms, and lung inflammation. Other recent studies also provide evidence of an association between elevated O_3 levels and increases in hospital admissions and emergency room visits, which signal significantly larger increases in doctor's visits, school absences, and lost work days. Further, animal studies demonstrate impairment of lung defense mechanisms and suggest that repeated exposure to O_3 over time might lead to permanent structural damage in the lungs, though these effects have not been corroborated in humans.

Based on this evidence, the CASAC Panel was in unanimous agreement that the present 1-hour standard should be eliminated and replaced with an 8-hour standard to focus on those exposures that are of most concern. The CASAC Panel also endorsed the range of 8-hour average concentrations (0.07 to 0.09 ppm) that EPA recommended for consideration. Further, the CASAC panel favored changing the form of the standard to one that allowed for multiple exceedances. Thus, CASAC's evaluation of the evidence is completely consistent with that of EPA, namely that all three major elements of the current O_3 standard should be revised, including the averaging time, the level, and the form.

In reaching a decision on the level and form for an 8-hour standard, EPA considered a number of complex public health factors. The quantitative assessments of exposures to levels of concern and of the risk of experiencing various effects indicated differences in public health protection among the various levels and forms considered, but they did not by themselves provide a clear break point for a decision. The quantitative assessments do, however, indicate that hundreds of thousands of children not protected under the current standard would be protected under EPA's proposed standard.

Also, consistent with EPA's prior decisions over the years, when setting an air quality standard for a pollutant for which there is no discernible threshold, factors such as the nature and

severity of the health effects involved, and the nature and size of the sensitive populations exposures are important considerations. Thus, EPA paid particular attention to the health-based concerns reflected in the independent scientific advice and gave great weight to the advice of the human health professionals on the CASAC Panel. Of the four human health experts on the CASAC Panel, three favored a level of 0.08 ppm and the other favored a level of either 0.08 or 0.09 ppm. No Panel members favored a standard level of 0.07 ppm; three others favored 0.09 ppm, and one favored either 0.09 or 0.10 ppm together with new public health advisories when the O_3 concentration was at or above 0.07 ppm. Thus, the proposed level of 0.08 ppm reflects the lowest level recommended by individual CASAC members; it gives great weight to the recommendations of the human health experts on the CASAC panel; and it is the lowest level tested and shown to cause serious health effects in controlled human-exposure health studies.

Finally, air quality comparisons have indicated that meeting a 0.08 ppm, third highest concentration, 8-hour standard (as proposed by EPA) would also likely result in nearly all areas avoiding days with peak 8-hour concentrations above the upper end of the range (0.09 ppm) referred to in the CASAC and the EPA staff paper. Given the uncertainties associated with this kind of complex health decision, EPA believes that an appropriate goal is to reduce the number of people exposed to O_3 concentrations that are above the highest levels recommended by any of the members of the CASAC panel. The form of the standard proposed (third highest daily maximum 8-hour average) appears to do the best job of meeting that goal, while staying consistent with the advice of the CASAC as a group, as well as the personal views of individual members.

For the reasons stated in the response to question 2(a)(i), EPA did not consider the costs of attaining the standard in developing the proposed standards. However, given the uncertainties inherent in forecasting future costs of control/prevention as well as the inability to fully quantify all of the known and potential benefits that are associated with reducing O_3 and its precursors, we do not believe that the benefits/cost analyses in EPA's draft RIA have shown that the costs of the proposed O_3 standards would outweigh the benefits.

Both EPA's Staff Paper and the Clean Air Scientific Advisory Committee's reports indicate that there are many unanswered questions and uncertainties about the potential health effects of fine particulates. There is no scientific evidence that establishes a causal relationship between fine particles and adverse health effects or explains how these particulates trigger and produce negative effects. Moreover, these documents indicate that the Agency is proceeding to set a standard with little baseline data on the current concentration levels or emissions of fine particulates.

7. Please explain in detail why EPA did not describe fully in its notice of proposed rulemaking the nature and significance of the concerns raised by its own Scientific Advisory Committee and EPA staff and why the Agency did not give appropriate weight to those concerns in evaluating whether the proposed $PM_{2.5}$ NAAQS will produce the health benefits that EPA has suggested.

The notice, in fact, discusses in detail both the strengths and limitations of the available scientific information on the effects of particle pollution on public health. The notice discusses the key issues raised during the criteria document and staff paper reviews in assessing community epidemiological studies, including alternative interpretations of the evidence, both for individual studies and for the evidence as a whole. The notice also makes clear at 61 FR 65641, third column, that "the relevant toxicology and controlled human studies published to date have not identified an accepted mechanism(s) that would explain how such relatively low concentrations of PM might cause the health effects reported in epidemiological literature." The discussion of the epidemiological studies (beginning at 61 FR 65644, third column) specifically notes alternative interpretations of individual study results. Further, it summarizes criteria document and staff paper evaluations of key scientific uncertainties and issues that must be addressed in appraising the available epidemiological evidence, including the effects of weather, co-pollutants, model specification, imprecision in measurement of ambient pollutants, and the use of such measurements as surrogates for population exposures. The notice further discusses (61 FR 65646) the consistency and the coherence of the health effects evidence. Based on a full evaluation of the issues associated with interpreting the individual studies together with the consistency and coherence among studies done in a variety of locations, the criteria

document - which was reviewed by CASAC - concluded that the available epidemiologic evidence suggested a "likely causal role of ambient PM in contributing to the reported effects (61 FR 65648, second column)."

The discussion of the risk analysis beginning at 61 FR 65650 also addresses key uncertainties that affect quantitative estimates of the health effects associated with PM. The notice provides a clear graphic illustration of one of the most important factors influencing the uncertainty associated with the risk estimates, namely whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur (Figure 2c. at 61 FR 65654, December 13, 1997).

In the discussion of the levels for the annual and 24-hour $PM_{2.5}$ standards, EPA considered both the strengths and limitations of the available evidence as well as alternative interpretations of the scientific evidence advanced by various CASAC panel members and public commenters, arising primarily from inherent uncertainties and limitations in the health effects studies. Because of the range of views that have been expressed by CASAC panel members and the public as to the appropriate public health policy response to available health effects evidence and related air quality information, the notice presents three alternative approaches to selecting appropriate standard levels. At one end of the spectrum, the notice articulates a very limited public health policy response, noting that several CASAC panel members supported such an approach (see footnote 30, 61 FR 65659, second column); the notice also solicits comment on a maximally precautionary response, as well as on the basis and rationale for the intermediate response proposed by the Administrator.

The EPA believes that, both in the preamble and in the expansive discussions in the staff paper and criteria document, it has given clear and appropriate weight to the scientific issues and concerns identified by CASAC and the EPA staff in evaluating the risks associated with PM and in developing the proposed standards themselves.

8. The EPA staff noted that "it is important to emphasize the unusually large uncertainties associated with establishing standards for PM relative to other single component pollutants

for which NAAQS have been set." Please explain why EPA is proceeding to set a standard in the face of such uncertainty when the Agency decided not to revise the NAAQS for sulfur dioxide and nitrogen dioxide.

The decisions not to revise the NAAQS for sulfur dioxide and nitrogen dioxide were based on a careful assessment of the scientific and technical information presented in the criteria documents and staff papers for those two pollutants, the advice and recommendations of CASAC, and the public comments received. The rationales for the sulfur dioxide and nitrogen dioxide decisions are discussed in detail in the notices of final action published at 61 FR 25566 (May 22, 1996) and 61 FR 52852 (October 8, 1996), respectively.

The decision to propose revisions of the current PM standards was based on careful assessment of the scientific and technical information presented in the PM criteria document and staff paper. The decision was also consistent with the consensus of CASAC that "although an understanding of health effects of PM is far from complete, the staff paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards." The extensive PM epidemiological data base provides evidence that serious adverse health effects (e.g., mortality, exacerbation of chronic disease, increased hospital admissions, respiratory symptoms, and pulmonary function decrements) in sensitive subpopulations (e.g., the elderly, individuals with cardiopulmonary disease, children) are attributable to PM at levels below the current standards. Although the increase in risk is relatively small for the most serious outcomes, it is significant from an overall public health perspective because of the large number of individuals in sensitive subpopulations that are exposed to ambient PM and the significance of the health effects. These considerations, as well as others discussed in the proposal notice and staff paper, such as the need to consider fine and coarse particles as distinct classes, led both the Administrator and CASAC to conclude that revision of the current standards is clearly appropriate.

9. Please list any peer-reviewed scientific studies that EPA considered in proposing the long-term $PM_{2.5}$ standard. Also, please provide the data underlying the Dockery (1993) and Pope

(1995) studies.

In developing proposed $PM_{2.5}$ standards, the Administrator believed that the suite of standards could be most effectively and efficiently defined by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations. Therefore, the full range of short- and long-term community epidemiological studies of the health effects of PM were considered in developing the proposed annual standard. Of the more than 80 such studies identified in the Criteria Document and Staff Paper, the Administrator placed greatest weight on those epidemiological studies reporting associations between health effects and direct measures of fine particles, most notably, those recent studies conducted in North America. As noted in the preamble, these studies are summarized in Tables V-12 and V-13 of the Staff Paper (see Enclosures F and G).

The data underlying the Dockery et al. (1993) and Pope et al. (1995) studies exist in component data bases: these include the health effects information on the cohorts studied, including information concerning time and cause of death, and the air quality measurements used to index exposures. The EPA does not have the health effects and mortality data sets in its possession. We have taken a series of steps, including contacting the original investigators, pursuant to earlier requests for these data. These are detailed in a February 13, 1997 letter from myself to Chairman Thomas Bliley (see Enclosure H). The EPA does, however, maintain in its possession a tabulation of the $PM_{2.5}$ data that served as the basis for the air quality data used in Pope et al. (1995). These data can be made available to the Committee. In addition, Pope et al relied on EPA-developed sulfate data in the AIRS database available on the Internet. The annual air quality data used in Dockery et al. (1993) is summarized in the study, but EPA maintains hard copies of the underlying particle data for some cities for some years. These data are over 3000 pages of computer printouts. We would be happy to make these data available to the Subcommittee. The EPA does not have an electronic copy of these data.

10. (a) Please explain in detail all the procedures EPA followed to validate the long-term mortality findings in the Pope study, and produce all records that document steps the Agency took to validate these findings.

The Pope et al. study, like the other peer-reviewed studies considered in this proposed rulemaking, was assessed explicitly in the criteria document (see Volume III, Chapter 12, pgs. 172-174). This assessment identified the various strengths and limitations of the study including exposure history, treatment of co-pollutants, and other factors. Section 12.4.1.4 discusses this study within the context of the studies on long-term mortality effects.

In this regard, it is important to note that a number of long-term studies have found significant associations between PM and mortality. The Pope et al. (1995) study was itself an attempt to validate - on a sufficiently large population cohort - the findings of the earlier but smaller cohort study by Dockery (1993), which itself represented an improvement over earlier cross-sectional studies of PM and mortality. Beyond the extensive analysis documented in the Criteria Document and Staff Paper, EPA did not conduct any independent assessment of the underlying data contained in the Pope et al. (1995) study nor do we feel that such an assessment is necessary given that the study has already been subject to numerous peer reviews.

(b) Please explain why EPA did not identify and discuss completely the limitations and uncertainties of the Pope study in its notice of proposed rulemaking. In particular, why didn't the Agency disclose that the risk ratio found in the Pope study is generally considered by the scientific community to be small, suggesting a weak statistical association between particulate pollution and mortality? Why did EPA not disclose that the Pope study did not measure how much air pollution subjects were actually exposed to? Why did the Agency not disclose that the observed relationship between particulate pollution and mortality rests entirely on epidemiology and is not supported by any other evidence, such as toxicological studies? Why did the Agency not disclose that the study did not adjust for variables in the subjects' diet, income, and health history, and used crude measures for others? Why didn't EPA disclose the difficulty of disentangling independent effects or potential interactions between highly correlated risk factors? Why didn't EPA disclose

the inability to fully explore the relative health impacts of the various constituents of particulate pollution?

The Federal Register preamble on PM addresses, in summary fashion, all of the salient strengths, weaknesses, and uncertainties associated with the health effects evidence on PM. Because the epidemiologic studies were so numerous, the preamble makes a number of points that are relevant to the studies as a group, rather than dealing with each study individually. As noted above, the Pope et al. (1995) study, like the other peer-reviewed studies considered in this proposed rulemaking, was fully assessed and evaluated in the criteria document and staff paper. The preamble restates these more detailed assessments in summary fashion and refers back to them as providing the basis for the Administrator's proposed decisions.

The general discussion of PM health effects and epidemiology in the PM preamble makes several overarching points about the available scientific data. It frames the general discussion of the recent evidence on mortality and morbidity (Section II.A, 61 FR 65641) with an introductory statement making clear that the toxicologic and controlled human data have not identified an accepted mechanism that would explain the observed epidemiologic findings. The evaluation of the evidence at 61 FR 65644 repeats this point in explaining the focus on the epidemiologic evidence. Further, the initial discussion of mortality studies makes clear that the magnitude of the relative risks is "small compared to those usually found in epidemiologic studies of occupational and other risk factors" (61 FR 65642).

As noted in the response to question 10 (a) above, the evaluation and assessments in the Criteria Document fully identified the strengths and limitations of the Pope et al. (1995) and related long term cohort studies, including issues relating to exposure history, treatment of potential confounders such as co-pollutants and other factors. The preamble summary of the evaluation for this specific study notes the magnitude of the relative risks reported and pointed out the concerns regarding the adequacy of adjusting for important confounders in this and other long term studies. In restating the criteria document conclusions that it is unlikely that these studies overlooked plausible confounders, the preamble also points out that the addition of potential additional confounders could alter the

magnitude of the association (61 FR 65642). The preamble explicitly notes the possible impact of the particular measures of air pollution exposures used in the Pope et al. (1995) and Dockery et al. (1993) studies, stating that "the magnitude of the relative risks associated with PM concentrations reported in these studies may be overestimated because some of the effects may be due to historical PM concentrations that were significantly higher than the ones used to estimate population exposures in these studies" (61 FR 65642).

The additional issues inherent in the appraisal of even the best long-term mortality studies tend to be greater than those for short-term studies for which certain factors (e.g., socioeconomic status and related lifestyle factors such as smoking) are clearly less troublesome (61 FR 65660). The existence of improved long-term cohort studies and the findings of increased risk of mortality in similar sensitive population groups in both short- and long-term studies serves to strengthen the credibility of the long-term studies. This is one of the reasons EPA relied on the findings from the daily studies together with the results from long-term studies in proposing the annual $PM_{2.5}$ standard (61 FR 65660).

The general difficulty in separating the effects of specific fine particle components from other fractions of PM and other pollutants is also addressed in the preamble, principally in Section II.A.4 and Section II.D. As noted therein, based on the available scientific information relating to the several specific components of fine particles, "it is not possible to rule out any one of these components as contributing to fine particle effects" (61 FR 65654). The EPA does not believe it was necessary to restate this conclusion each time any of the studies was discussed in the preamble.

11. Please explain in detail how EPA believes it is possible to determine whether a fine particulate standard is necessary without addressing significant scientific uncertainties and data gaps in the areas of epidemiology, exposure, $PM_{2.5}$ monitoring, and biological mechanisms.

The Administrator detailed her rationale for proposing to add a fine particle standard in the Federal Register preamble, most notably at 65 FR 65654-65662. It is based on the extensive

review of the science and policy issues contained in the PM criteria document and staff paper; the CASAC concluded, after extensive review, that both of these documents were appropriate for use in decision making on standards. These documents contain a full discussion of both what is known about PM and the information gaps and uncertainties. Considering all the scientific evidence, including the uncertainties, it was the clear consensus of the CASAC PM Panel (19 of 21 panelists), including representatives of each of the multiple scientific disciplines included on the panel, that a new $PM_{2.5}$ standard should be established. A decision not to establish a fine particle standard would ignore the advice of these Congressionally mandated science advisors.

12. In light of the significant scientific deficiencies and limited database, how does the Agency explain its undertaking a review of the existing PM_{10} standard in far less time than for earlier particulate standards before recommending the setting of a new $PM_{2.5}$ standard.

The original examination of the Criteria Document for Particulate Matter (DHEW, 1969) led to promulgation of the original TSP standards in 1971. The first formal review of the PM criteria and standards was announced in 1979. A careful examination of the record reveals that the time allotted for the scientific assessment phase of that review, which concluded with EPA staff and CASAC recommendations for new standards, was nearly identical to that for the present review.

The first review of the PM NAAQS formally commenced with an October 1979 announcement in the Federal Register. That review was in fact complicated by the decision to prepare a joint criteria document that addressed both PM and sulfur oxides (SO_x), though the subsequent reviews of the PM and SO_x standards by EPA staff and CASAC dealt with the two pollutants separately. Following the announcement, EPA developed three successive drafts of the criteria document for review by CASAC and the public, interspersed with several workshops on different sections of the document. The CASAC issued a closure letter on the criteria document in January 1982, following the last public meeting on the document in November 1981. After public meetings on two drafts of the staff paper for PM, CASAC issued its closure letter on the staff paper in January 1982. In that letter to

Administrator Gorsuch (Friedlander, 1982; see Enclosure J), CASAC recommended that the Administrator make major revisions to the PM standards. Thus, the scientific assessment phase of the first review of the standards, including CASAC's rendering of advice and recommendations for new standards, was completed two years and three months after the initial announcement.

The present review of the PM standards formally commenced with a Federal Register announcement in April 1994. Following that announcement, EPA held several workshops on aspects of the document, and developed three successive drafts of all or portions of the criteria document for review by CASAC and the public. The CASAC issued a closure letter on the criteria document in March 1996, following the last public meeting on the document in February of that year. After public meetings on two drafts of the staff paper for PM, CASAC issued its closure letter on the staff paper in June 1996. In that letter, CASAC recommended major revisions to the PM_{10} standards, including its recommendation that one or more standards be established for fine particles. Thus, the scientific assessment phase of the present review, including recommendations by CASAC and staff for new standards, was completed two years and two months after the initial announcement. This is only one month less than it took to reach the comparable point in the previous review.

It is true that in the prior review it took an additional two years, beyond CASAC closure on the science, to propose revision of the original standards, with an extended time between proposal and promulgation that added three more years. However, this is hardly a model for NAAQS reviews. The delay between CASAC closure on the science in January 1982 and the proposal in 1984 was not occasioned by the need for further scientific assessment, but by the focus of Agency decision makers on unrelated issues, including a change in Agency management and the transition to a new Administrator and Assistant Administrator. Ultimately, the process stretched to such a degree that, for both PM and sulfur oxides, it was deemed appropriate to update the criteria document and staff papers to reflect additional scientific findings. These did not alter the fundamental components of the CASAC recommendations or the proposed decisions on PM.

As indicated in the Federal Register notice proposing

revision of the existing standards for PM, the EPA has been under a court order imposing a schedule for completion of the current review. American Lung Association v. Browner, CIV-93-643-TUC-ACM (D. Ariz., October 6, 1994). As you may be aware, EPA has sought and obtained modifications of the court order on four separate occasions to extend the times specified for completion of various tasks, including publication of the proposal notice in the Federal Register. The Court has now indicated that no further extensions will be granted.

Notwithstanding the constraints imposed by the court order, EPA has conducted a thorough, comprehensive review of the scientific criteria and standards for PM. The procedures permitted full public participation in the process, and the time taken was commensurate with that taken in the previous review.

13. Please explain the urgency that EPA has placed on setting a new particulate standard during the current review cycle rather than deciding not to add a new standard before the science has been developed to inform the Agency about which particulates, in which geographical locations, and in which concentrations, may be harming health and the environment. Isn't a better understanding of the health effects of particulates needed before effective control strategies can be designed?

This question is closely related to question 11. Again, considering the full weight of the scientific evidence, including the uncertainties, the CASAC recommended that the Administrator adopt fine particle standards. The EPA agrees in particular with a number of panel members who based their support for a $PM_{2.5}$ standard on the following reasoning:

> [T]here is strong consistency and coherence of information indicating that high concentrations of urban air pollution adversely affect human health, there are already NAAQS that deal with all of the major components of that pollution except $PM_{2.5}$, and there are strong reasons to believe that $PM_{2.5}$ is at least as important as $PM_{10-2.5}$ in producing adverse health effects [Wolff, 1996; see Enclosure K].

Given the consistency and coherence of the evidence that premature mortality and sickness to large numbers of Americans is occurring at concentrations permitted by the current standards,

the Administrator believes it would be irresponsible to delay action that would put more appropriate air quality goals into place based on the most recent scientific information.

Examination of the available scientific evidence to date does not suggest that any single component of fine particles will turn out to be responsible for all of the effects associated with PM. Indeed, it is more likely that multiple components may play multiple roles in producing effects.

14. As Ranking Member Dingell, Chairman Chafee and others have pointed out, States are in a critical stage of implementing their State implementation plans under the Act. Changing direction mid-course may significantly delay or run counter to current efforts underway to assure reasonable further progress in attaining air quality standards.

(a) Please describe in detail how the timetables for implementation of the proposed NAAQS would affect States' compliance with deadlines for implementing current standards.

The EPA does not believe that the promulgation of new O_3 or PM standards will undercut current efforts to assure reasonable further progress in attaining air quality standards. In the instance of O_3, to facilitate continuity in public health protection during the period of transition to a new standard, EPA has proposed that, except for two limited purposes, the effective date of the revocation of the current O_3 standard would be deferred until EPA determines that an area's SIP provides for the achievement of the new standard. The two exceptions to the general deferral of the effective date of the revocation of the existing O_3 NAAQS would be attainment demonstrations and reclassifications. See 61 Fed. Reg. At 65733. Also, on December 13, 1997 (61 FR 65752), EPA published a notice of proposed policy to cover the interim period following promulgation of new or revised O_3 and PM NAAQS. The proposed policy is premised on a no-backsliding concept and is intended to ensure that momentum is maintained by the States in the current program while moving toward developing plans for implementing new or revised NAAQS. The interim policy would take effect on the date of the NAAQS promulgation and remain effective in each area until the effective date of EPA approval of the SIP revision for achieving the new NAAQS. The impact of the policy and the deferred

revocation of the O_3 NAAQS would be to assure that the promulgation of new standards would not impede progress towards attainment of the NAAQS.

As a general matter, under the proposed interim implementation policy and with the deferred revocation of the current O_3 NAAQS, current deadlines for State SIP submittals would not be extended as a consequence of the promulgation of new NAAQS. The only instances in which the promulgation of a new NAAQS would have such an effect are with respect to the two purposes for which revocation of the O_3 NAAQS would not be deferred--attainment demonstrations and reclassifications. As explained in greater detail in the December 13, 1996 proposal (61 Fed. Reg. at 65754), EPA believes (1) that the requirement to designate attainment of the existing NAAQS will be superseded by a requirement to demonstrate attainment of the new NAAQS by new dates, and (2) that in the case of reclassifications, areas need not have to adopt the additional specified control measures they would have to adopt under the current reclassification system provided they achieve the same rate of progress in terms of emission reductions that they would have had to achieve after a reclassification.

Subpart 1 of part D of the Act sets out the time frames which govern the implementation of both new ozone and a new fine particle standard. Assuming that promulgation of the ozone and fine particle NAAQS occurs in July 1997, nonattainment area designations should follow in mid-1999 or 2000, since designations are to occur no later than 2 years after promulgation of the NAAQS (or up to 3 years if there is insufficient information to designate). Under this scenario, the nonattainment area SIPs would be due in the mid-2002 or mid-2003 time frame, because they are due 3 years after the nonattainment designations occur. In the Act, attainment dates for newly designated nonattainment areas may be extended 10 years from the nonattainment designations, i.e., in this case they could be extended to 2010. In addition, areas may be granted up to 2 one-year extensions of the attainment date if certain criteria are met. In light of EPA's proposed approach to implementation of the new NAAQS during the interim period prior to the submission and approval of the new SIP's, EPA does not believe that these deadlines would have a negative effect on progress towards attainment.

(b) Do you believe that the current timetables for monitoring, planning and attainment demonstration would be appropriate for implementing these proposed standards concurrently?

The EPA believes it is appropriate to integrate implementation of the O_3 and PM NAAQS because of the linkages in atmospheric chemistry; e.g., many of the emission precursors to O_3, fine particles and regional haze are the same. In addition, integration is expected to result in optimization of control measures to accomplish attainment of both the O_3 and PM NAAQS and to meet regional haze goals, thereby minimizing costs.

As you know, EPA has established a FACA subcommittee to provide advice and recommendations to EPA on developing new, integrated approaches for implementing new or revised O_3 and PM NAAQS. Any recommendations to EPA from the subcommittee will be considered in developing an implementation program for a new or revised NAAQS. Since the subcommittee has just begun Phase II of this effort, which addresses long-range transport and control strategies and their timing, it is not possible at this time to determine the precise nature or the implementation timetable of the controls needed for areas to meet new or revised standards.

15. <u>If the only way</u> to implement EPA's proposed new or revised ozone and PM NAAQS was to prohibit family barbecues, family woodburning fires, and gasoline lawn mowers, and to require forced carpooling and other driving restrictions, would EPA continue to consider adopting these standards?

The control measures you mentioned in your letter, which we agree would be unpopular with the public, have not been addressed by the Subcommittee to date. EPA has no intention of adopting the types of measures described above.

16. I understand that EPA has established a Federal Advisory Committee Act (FACA) process to provide advice and recommendations to the EPA on developing new, integrated approaches for implementing proposed NAAQS for ozone and PM. Please provide a list of the FACA participants, broken down by the sectors of society that they represent (i.e., specify State, local and tribal organizations, environmental groups, industry and trade groups, small business representatives, consultants, academic/scientific communities, and Federal agencies).

As you requested, enclosed (see enclosure L)is the current list of the Subcommittee mentioned above. Note that the members of the Subcommittee are grouped by the sector which they represent and that EPA is in the process of adding additional representatives of small businesses.

I appreciate this opportunity to be of service and trust that this information will be helpful to you.

Sincerely yours,

Mary D. Nichols
Assistant Administrator
for Air and Radiation

Enclosures (A-L)
Records Inventory and Records

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

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

FEB 1 1 1997

The Honorable David M. McIntosh
Chairman, Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
Committee on Government Reform and Oversight
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter of January 17, 1996, regarding the Office of Information and Regulatory Affairs' (OIRA) review of the Environmental Protection Agency's (EPA) recently proposed revisions of the National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter.

You asked for certain information either through questions or document requests. Your questions are typed, below, in bold. Our responses follow. We will respond to your document requests soon.

1. **Please indicate the date on which EPA submitted its final package of four regulatory actions to OMB for review under Executive Order 12866. Also, please indicate the date on which EPA submitted its draft regulatory analyses for review.**

   We received the final package of four regulatory actions for the National Ambient Air Quality Standards (NAAQS) proposals for ozone and particulate matter on November 4, 1996. We received the draft regulatory analyses later that day.

2. **Please indicate the amount of time that the Office of Information and Regulatory Affairs (OIRA) spent on reviewing each regulatory action and supporting documents. Please provide the total amount of staff hours and the number of staffers devoted to such review and the total number of elapsed days devoted to such review for each of three different phases of the proposed rulemaking process: (a) the time OIRA spent reviewing drafts of the proposed rules prior to the date EPA submitted its final package of proposed rules under Executive Order 12866, (b) the time OIRA had to review the final package of proposed rules from the date of EPA's submission until the time OIRA cleared the rules for publication in the Federal Register (we believe this was roughly a three-week period of time), and (c) the amount of time you have spent reviewing the proposed rules since the time you cleared the proposed rules for publication until the date of your response to this request for information.**

We do not maintain time sheets or any other record of the amount of time devoted to review of any particular rule or its supporting documents. The following response, therefore, is based on my recollection and those of my staff.

(a) Before the date that EPA submitted its final package of proposed rules, OIRA staff attended a number of meetings at which EPA explained in general terms the methodology it was using in its analysis of these rules (e.g., data, assumptions, models, etc.). In addition, EPA and OIRA staff hosted a number of interagency meetings with EPA staff briefing other Federal agencies on the general issues surrounding EPA's review of the ozone and particulate matter NAAQS. In total, EPA informs us there were about 18 such meetings -- one in 1993, five in 1994, three in 1995, and nine in 1996. There were no drafts of these proposed rules reviewed at these meetings. We cannot reasonably estimate the OIRA staff hours involved because of the long time period covered and the episodic nature of the work.

(b) OIRA concluded its review of the four proposed rules on November 26, 1996, 22 days after we received them; as explained further below in response to question 3, EPA was under a court-ordered deadline to issue the particulate matter NAAQS proposal by November 29, 1996. In order to complete our review during this period, OIRA devoted considerable staff resources and time to the rules, working intensively late in the evening and on weekends. The OIRA staff team was composed of the Branch Chief for Natural Resources, along with three desk officers and one economist. During the review period, the Branch Chief spent approximately one-third to one-half of his time on the rules, while the other staff spent approximately the following portions of their time on the rules (one desk officer: three-fourths of his time; the other two desk officers: one-third to one-half of their time; the economist: substantially all of his time). During the review period, I spent approximately half of my working time on these rules.

(c) With respect to the period between November 26, 1996 (when OIRA concluded its review of the proposed rules) and February 7, 1997, my staff inform me that they have continued to devote a significant amount of time to their assessment of these rules, although not as much (as a portion of their overall time) as during the review period. I also devoted additional time to these rules in relatively small increments of time over this two and a half month period.

3. **Please explain in detail why OMB did not insist upon or otherwise ensure that it would have a 90-day review period in light of the complexity of these proposed rules. In particular, please explain in detail: (a) why OMB did not ensure, through discussions with appropriate EPA and White House officials, that OMB/OIRA would have a more extended period for reviewing the proposed particulate rules prior to the judicial deadline of November 29, 1996 for EPA action, and (b) why OIRA did not take an extended amount of time to review the proposed ozone standard and interim implementation policy.**

We originally expected EPA to submit the draft proposed rules to OMB for review in early September. EPA originally presented a schedule to the court that would have allowed 90 days for OMB review. The court specifically deleted the time separately set for the OMB review; the OMB review time came out of the total time allotted to EPA by the court. As it became apparent that the date for the submission of the proposals to OMB would slip, I made a number of requests to EPA to submit these proposals as soon as possible.

(a) I should note, in answering this question, that EPA had a court-ordered deadline to promulgate the particulate matter NAAQS proposal by November 29, 1996. In its effort to comply with E.O. 12866, EPA sought to accelerate its work so as to provide OMB time for its review within the period of time allowed by the court.

EPA was fully aware that it was important to provide OMB with copies of the draft proposed rules and accompanying analyses as soon as possible. As I indicated in my January 15, 1997, letter to Chairman Bliley, I believe that further questions about the timing of EPA's submission of the proposed rules to OIRA can best be responded to by EPA.

(b) Although EPA had no court-ordered deadline for the ozone NAAQS, it wanted to publish the proposed ozone standard with the proposed particulate matter standard. Among other things, I am advised by EPA that they believed that simultaneous publication of the two proposals, both of which related to air quality, would allow the regulated community and other interested entities to evaluate each of the proposals with the other in mind and to consider how the two proposals would interact.

4. **In your January 15, 1997 letter, you stated that you made "a number of requests to EPA to submit [the] proposals [earlier] so as to provide OMB and other Federal agencies with time to properly review them," but EPA refused your numerous requests. (a) Please explain in detail whether OMB has sufficient support from the President and senior White House officials to ensure compliance with your reasonable requests under Executive Order 12866. (b) If you answer to request 4(a) is that OMB has the sufficient support from the President and senior White House officials to back-up your reasonable requests under Executive Order 12866, what statutory provisions could we enact to ensure actual agency compliance with your requests?**

(a) I believe that, during my tenure as OIRA Administrator, OMB in general, and OIRA in particular, have had sufficient support from the President and the White House staff to ensure the effective implementation of E.O. 12866.

(b) I do not believe that any statutory provision "to ensure actual agency compliance" with our requests is either necessary or advisable.

5. **Please indicate the number of days and the approximate number of staff hours that OIRA devoted to reviewing EPA's 1994 reproposal of the air quality standard for**

sulfur dioxide, which also was subject to court-ordered deadline, prior to its publication as a proposed rule.

EPA's 1994 draft reproposal of the air quality standard for sulfur dioxide was received on September 21, 1994. OIRA concluded its review of this reproposal on October 28, 1994, 37 days after it was received. OIRA staff recollect that they spent a modest amount of time reviewing this rule; I do not remember how much time I may have spent on this rule.

Nature and Scope of Review

6. **Based on its 90-day or longer review of analogous proposed rules, please explain how OIRA's review of EPA's regulatory actions and the accompanying analyses would have differed if OIRA has used a 90-day or longer review period before the proposed rules were cleared for publication in the Federal Register.**

While the review period for the proposed rules was only 22 calendar days, I believe the OIRA review was very intense -- much more intense than any other three week period during a 90-day review. The shortness of time, however, precluded full discussion and resolution of some of the issues identified by the OIRA staff before the court-ordered deadline. We have been advised by EPA that these issues will be analyzed as part of the economic analyses for the final rules.

With more calendar time, presumably we would have spread out our efforts. I should note that we did have more time to review the accompanying analyses, concluding our review on December 6, 1996.

7. **Please provide a detailed explanation of and produce all available documents indicating the procedures that OIRA followed in undertaking its review of the proposed rules.**

The procedures OIRA followed in undertaking its review of the proposed rules are outlined in E.O. 12866.

10. **(a) Please explain in detail why OIRA cleared the proposed rules for publication when EPA had not complied with the requirements of the Regulatory Flexibility Act. (b) Please indicate whether or not OMB takes the position that an initial regulatory flexibility analysis, and other actions under the Regulatory Flexibility Act, were not required by law for the proposed rules.**

(a) In the preambles to both rules, EPA stated that it did not believe that either the particulate matter or the ozone NAAQS would have a significant economic impact on small entities within the meaning of the Regulatory Flexibility Act. EPA explained that the NAAQS establish a standard of air quality; that the requirements necessary to achieve these standards

is to be set forth in a future implementing regulation; and that this latter regulatory action would have an effect on small entities, and so the Regulatory Flexibility Act would apply to that latter regulatory action.

(b) Under the Regulatory Flexibility Act, the "Chief Counsel for Advocacy of the Small Business Administration shall monitor agency compliance" with this Act (5 U.S.C. 612). Questions about EPA compliance with the Regulatory Flexibility Act can best be responded to by EPA and SBA.

11. Please specify the amount of time within which other interested administrative agencies had an opportunity to review and provide input on the draft written regulatory package through the interagency review process. Please provide copies of any written comments and records of communications from such agencies.

As I indicated in my response to question 2(a), the other agencies participated in meetings hosted by EPA and OIRA staff before November 4, 1996, at which EPA staff briefed the other agencies on the general issues surrounding EPA's review of the ozone and particulate matter NAAQS. It is our understanding that other agencies received the package of four draft proposed rules for review at about the same time as OIRA.

I hope that this responds to your request.

Sincerely,

Sally Katzen

Sally Katzen

cc: The Honorable Henry A. Waxman

November 30, 1995

EPA-SAB-CASAC-LTR-96-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

RE: CASAC Closure on the Primary Standard Portion of the Staff Paper for Ozone

Dear Ms. Browner:

A Panel of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) met on March 22, 1995, to review a draft of the primary standard part of the document entitled Review of National Ambient Air Quality Standards for Ozone Assessment of Scientific and Technical Information OAQPS Staff Paper. At that time, a draft of the secondary standard portion of the document was not completed. At the March meeting, the Panel made extensive recommendations for strengthening the document. In August 1995, a revised Staff Paper, which included a first draft of the secondary standard portion was sent to CASAC panel members for review. On September 19 and 20, 1995, the Panel met to compete this review. The Panel members' comments reflect their satisfaction with the improvements made in the scientific quality and completeness of the primary standard portion of the Staff Paper. The changes made in that portion of the document are consistent with CASAC's recommendations. However, the Panel Members provided additional comments to your staff at the meeting and subsequently in writing. Although the Panel would like to have these comments considered for incorporation in the Staff Paper, the Panel did not feel that it was necessary to review another revised version and came to closure on the primary standard portion. It was the consensus of the Panel that although our understanding of the health effects of ozone is far from complete, the document provides an adequate scientific basis for making regulatory decisions concerning a primary ozone standard.

The Panel could not come to closure, however, on the secondary standard portion of the Staff Paper which was a first draft. To facilitate further development of this part of the Staff Paper, the Panel members have provided detailed comments to your staff. The Panel felt that the suggested revisions were extensive enough to warrant a review of the next draft.

I would like to summarize for you the Panel's recommendations concerning the primary standard. It was the consensus of the Panel that EPA's selection of ozone as the surrogate for controlling photochemical oxidants is correct. It was also the

consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard. The Panel was in unanimous agreement that the present 1-hour standard be eliminated and replaced with an 8-hour standard.

The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations. This means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an "adequate margin of safety" is no longer possible. It further means that EPA's risk assessments must play a central role in identifying an appropriate level.

To conduct the risk assessments, the Agency had to identify the population at risk and the physiological responses of concern, develop a model to estimate the exposure of this population to ozone, and develop a model to estimate the probability of an adverse physiological response to the exposure. The Panel agrees with EPA that the selection of "outdoor children" and "outdoor workers," particularly those with preexisting respiratory disease are the appropriate populations with the highest risks. After considerable debate, it was the consensus of the Panel that the Agency's criteria for the determination of an adverse physiological response was reasonable. Nevertheless, there was considerable concern that the criteria for grading physiological and clinical responses to ozone was confusing if not misleading. The Panel concurs, with the Agency that the models selected to estimate exposure and risk are appropriate models. However, because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in these estimates.

The results of two of the risk analyses are presented in Tables VI-1 and VI-2 in the Staff Paper and are reproduced in the attached tables. The ranges of the risk estimates across nine cities for outdoor children are presented in Table VI-1. Because of the large number of stochastic variables used in the exposure models, the exposure estimates vary from run to run. However, the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.

The single estimates presented in Table VI-2 do not reflect any of the uncertainties associated with these estimates. (Table VI-2 contains only the estimated hospital admissions due to asthma which account for over 85% of the estimated total hospital admissions due to ozone exposure). These uncertainties need to be explicitly articulated in order to put the estimates in proper perspective. Nevertheless, based on the results presented in these and other similar tables presented in the Staff Paper, the Panel concluded that there is no "bright line" which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health. For example, the differences in the

percent of outdoor children (Table VI-1) responding between the present standard and the most stringent proposal (8H1EX at 0.07 ppm) are small and their ranges overlap for all health endpoints. In Table VI-2, the estimates in row 1, which appeared in the draft Staff Paper, suggest considerable differences between the several options. However, when ozone-aggravated asthma admissions are compared to total asthma admissions (rows 5 and 6), the differences between the various options are small. Consequently, the selection of a specific level and number of allowable exceedences is a policy judgment. Although it was the consensus of the Panel that the ranges of concentrations and allowable exceedences proposed by the Agency were appropriate, a number of Panel members expressed "personal" preferences for the level and number of allowable exceedences. Of the ten panel members who expressed their opinions, all ten favored multiple allowable exceedences, three favored a level of 0.08 ppm, one favored the mid to upper range (0.08 - 0.09 ppm), three favored the upper range (0.09 ppm), one favored a 0.009 - 0.10 ppm range with health advisories issued when the 8-hour ozone concentration was forecasted to exceed 0.007 ppm, and two just endorsed the range presented by the Agency as appropriate and stated that the selection should be a policy decision. The members who favored the lower numbers expressed concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies and the observations of pain on deep inspiration in some subjects.

Because there is no apparent threshold for responses and no "bright line" in the risk assessment, a number of panel members recommended that an expanded air pollution warning system be initiated so that sensitive individuals can take appropriate "exposure avoidance" behavior. Since many areas of the country already have an infrastructure in place to designate "ozone action days" when voluntary emission reduction measures are put in place, this idea may be fairly easy to implement.

It was also the consensus of the Panel that the form of the 8-hr standard be more robust than the present 1-hour standard. The present standard is based on an extreme value statistic which is significantly dependent on stochastic processes such as extreme meteorological conditions. The result is that areas which are near attainment will randomly flip in and out of compliance. A more robust, concentration-based form will minimize the "flip-flops," and provide some insulation from the impacts of extreme meteorological events. The Panel also endorses the staff recommendation for creating a "too close to call" category.

Since the last ozone NAAQS review, the scientific community has made great strides in their understanding of the health effects of ozone exposure because of ongoing research programs. Panel members were very impressed with how much more we understand now as compared to the prior round. Nevertheless, there are still many gaps in our knowledge and large uncertainties in many of the assessments. For example, there is little information available on the frequency of human activity patterns involving outdoor physical exercise. Little is also known about the possible chronic health impacts of ozone exposure over a period of many years. In addition, there is no

clear understanding of the significance of the inflammatory response inferred from the broncholavage data. Panel members stated, however, that the scientific community is now in a position to frame the questions that need to be better resolved so the uncertainties can be reduced before the next ozone review in 5 years. For this reason, it is important that research efforts on the health and ecological effects of ozone not be reduced because we have come to closure on this review.

CASAC would appreciate being kept informed of progress on establishing a revised or new ozone standard, and plans for research on ozone effects. Please do not hesitate to contact me if CASAC can be of further assistance in this matter. We look forward to receiving the revisions of the secondary standard portion of the Staff Paper.

Sincerely,

Dr. George T. Wolff, Chair
Clean Air Scientific Advisory Committee

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Table VI-2 (revised)

ESTIMATED HOSPITAL ADMISSIONS FOR ASTHMATICS IN THE NEW YORK CITY AREA

1H1EX
0.12
1H1EX
0.10
8H1EX
0.10
8H1EX
0.09
8H1EX
0.08
8H1EX
0.07
8H5EX
0.09
8H5EX
0.08
AS IS

Excess Admissionsa
210
130
240
180
110
60
180
120
=385d

% ^ from present std
0%

-38%
+14%
-14%
-48%
-71%
-14%
-42%
+83%

Excess + backgroundb
890
810
920
860
790
740
860
800
1065e

% ^ from present std
0%
-9%
+3%
-3%
-11%
-17%
-3%
-10%
+20%

All asthma admissionsc
28,295
28,215
28,325
28,265
28,195
28,145
28,265
28,205
28,470f

% ^ from present std
0%
-0.3%
+0.1%
-0.1%
-0.4%
-0.5%
-0.1%
-0.3%
+0.6%

a - excess asthma admissions attributed to ozone levels exceeding a background concentration of 0.04 ppm; from Table VI-2, page 155 in the
August 1995 OAQPS Draft Staff Paper
b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = 1065e - 385d = 680
c - asthma admissions due to all causes = 28,470f - 385d - Excess Admissions from row 1
d - estimated from Figure V-15, page 125 in the August 1995 OAQPS Draft Staff Paper
e - from page 127, line 13 in the August 1995 OAQPS Draft Staff Paper
f - total admissions from asthma = total asthmatics (365,000 - from page 126, line 24) x hospitalization rate (78/1000 asthmatics - from page 126,
line 29

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Dr. Roger O. McClellan, Chemical Industry Institute of Toxicology, Research Triangle Park, NC

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