Pace Environmental Law Review

Volume 16
Issue 1 *Winter 1998*

Article 5

January 1998

Scientific Research for Ozone and Fine Particulate Matter

John Vandenberg

Scientific Research for Ozone and Fine Particulate Matter

DR. JOHN VANDENBERG*

It is my pleasure today to provide a brief overview of some of EPA's research program activities, especially as they relate to understanding the scientific issues affecting the assessment and management of ozone and particulate matter (PM) air pollutants. In my comments, I will provide a framework for air quality management, highlight some of the current data regarding the effects of ozone and PM on public health, and then present research needs and priorities, focusing on those associated with airborne particulate matter. Research is underway to address the highest priority research needs, the products of which include methods, models and data that will improve and expand the science to be considered in future reviews of the National Ambient Air Quality Standards (NAAQS), and will support standards implementation.

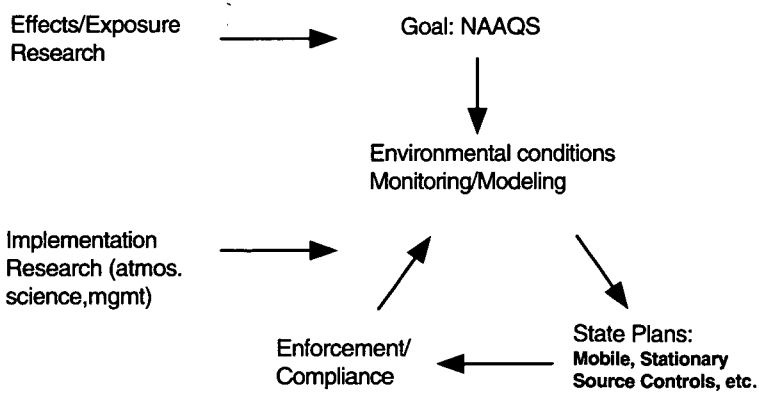
---

* Dr. Vandenberg is currently National Research Program Director for particulate matter and Assistant Director of the U.S. Environmental Protection Agency's National Health and Environmental Effects Research Laboratory, where he has primary responsibility for strategic planning and implementation of EPA's particulate matter research program. Prior to his current position, he served as an environmental scientist for the Pollutant Assessment Branch of EPA and for the Reproductive and Cancer Hazard Assessment Section of the California Department of Health Services. Dr. Vandenberg received his M.S. and Ph.D. in Biophysical Ecology from Duke University and he is currently an Adjunct Assistant Professor at the Nicholas School of the Environment. He is a member of the Society for Risk Analysis, the Air and Waste Management Association, and the American Meteorological Society. His writings regarding air quality and health risk assessment have been extensively published. This manuscript has been reviewed by the National Health and Environmental Effects Research Laboratory of the U.S. Environmental Protection Agency and has been approved for publication. The views and opinions are those of the author and do not reflect Agency positions or policy.

The framework for air quality management that is generally used in the United States is shown in Figure 1. As indicated, health and exposure research is used in establishing national air quality standards. Once standards are established, state and local agencies assess the condition of the environment, determine if an area is in attainment with the standards, and develop State Implementation Plans (SIPs) that set a course for the states toward meeting the standards. Research supports implementation of the standards through development of improved monitoring and modeling methods and control technology development and evaluation. This morning, the standards setting process was described by other speakers in some detail. I would like to build on the earlier presentations and discuss the way the review of the science not only supports standards review, but also benefits research planning.

Figure 1

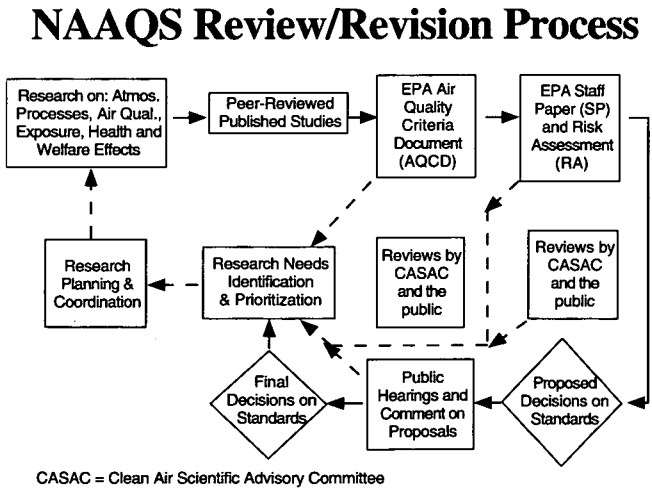
Framework for Air Quality Management



The NAAQS review and revision process is diagramed in Figure 2. To begin the process, data published in peer reviewed publications such as scientific journals are summa-

rized in an air quality criteria document (CD).[1] Dr. Thurston mentioned that this document is the thickness of approximately three Manhattan phone books. This document is reviewed by the Clean Air Scientific Advisory Committee (CASAC),[2] a group of prominent independent scientists who ensure that the data is properly represented and interpreted. Relevant information is then evaluated by the regulatory program, which produces a Staff Paper and risk assessment that interprets and utilizes the information from the CD in the context of standard setting. Again, the CASAC reviews the Staff Paper to ensure appropriate data interpretation. The Staff Paper serves as a link between the scientific criteria and the regulatory decision making process. A proposed NAAQS decision is made by EPA Administrator, which goes through public hearings and a review and comment process.[3] With due consideration to the public comments, the Administrator makes the final decisions on the standards.

Figure 2



1. *See* U.S. Envtl. Protection Agency, Air Quality Criteria Document for Ozone and Related Photochemical Oxidants, EPA/600/AP/93/004a-c (1996).

2. *See* Clean Air Act § 108(a)(2), 42 U.S.C. § 7408(a)(2) (1994).

3. *See* National Ambient Air Quality Standards for Particulate Matter, 40 C.F.R. pt. 50 (1997).

The dashed lines show that not only is the process moving toward standards setting, but also there is the simultaneous identification of research needs, which are documented to support research planning and prioritization.

Earlier today, someone suggested that EPA has more lawyers than scientists. I beg to differ. We have a large and vigorous scientific research program. In EPA's National Health and Environmental Effects Research Laboratory alone, we have fifty scientists working full time on particulate matter research. My laboratory is just one of the three EPA laboratories engaged in PM research which, together, focus on the highest priorities and produce scientific results important to the review and standards implementation processes.

So, what does the current data show? Dr. Thurston reviewed the science underlying the proposed and final standards for ozone and PM. Therefore, I will briefly discuss the scientific basis for these standards. In the case of ozone, the scientific basis for the standards includes the following:

> the extensive review of thousands of scientific studies, which identified more than one hundred and eighty key health effects studies as a basis for the new (1997) NAAQS;
>
> these studies indicate that ozone levels below the pre-1997 NAAQS (i.e., 0.12 parts per million for one hour) can cause significant health effects in children and other susceptible groups.

The effects from ozone include:

> moderate (~15%) to large (>20%) decreases in lung function (resulting in, e.g., difficulty in breathing or shortness of breath);
>
> respiratory symptoms such as those associated with chronic bronchitis (e.g., aggravated/prolonged coughing and chest pain);
>
> increased respiratory problems (e.g., aggravation of asthma, susceptibility to respiratory infection) resulting in increased hospital admissions and emergency room visits;
>
> repeated exposures could result in chronic inflammation and structural changes in the lungs;
>
> growing evidence suggests an association with premature death.

Based on a review of the scientific data, the CASAC unanimously recommended that EPA replace the one-hour standard with an eight-hour standard to protect against longer exposures (six to eight hours) related to health effects at lower concentrations under more typical exposure conditions.

The bottom line is that scientific data are summarized, evaluated and reviewed by CASAC to ensure that the standards have a scientific basis.

I would like to share one point that has arisen from our studies. In EPA research facilities, we study volunteers in a clinical setting. Often they are healthy college students, though we also conduct studies with children and people who have preexisting cardiopulmonary and other diseases. What we have found is that among a seemingly 'normal' population, some individuals respond quite dramatically to relatively low ozone exposures, while others are not apparently affected much, if at all, at relatively high exposure levels. To use an example, there are perhaps sixty people in the audience today. Some of you, including individuals who are not asthmatics, are likely to respond to low ozone exposures; others would not. We cannot, at this time, tell which of you will respond, but we have found that there is a broad distribution in response among the population. It is not clear to us why some people in the general population respond to ozone and others do not. The NAAQS are intended to protect more susceptible subpopulations. We have yet to develop a biomarker or other indicator that tells us who are the responders, and who are not. Finally, I would like to reinforce the point that responses we are seeing are in people like you and me. These results do not represent an extrapolation from animal studies, though we use animal studies to help elucidate mechanisms of cause-effect and to explore factors affecting susceptibility.

I now will turn my comments to particulate matter. Again, there are many studies of the health effects of PM. For PM, the scientific basis for the standards includes the following:

an extensive review of thousands of scientific studies identified more than eighty epidemiological studies as the basis for the revised standards;

more than sixty epidemiological studies found significant links between PM levels at or below the current standards and premature death or serious illness;

numerous studies indicate "fine" (i.e., $PM_{2.5}$)[4] and "coarse" ($PM_{2.5-10}$)[5] fractions of PM_{10} behave in fundamentally different ways.

The effects from PM exposures include:

increased premature deaths, primarily in the elderly and those with heart or lung disease;

aggravation of respiratory and cardiovascular illness leading to hospitalizations and emergency room visits in individuals with heart or lung disease and in children;

lung function decrements and symptomatic effects such as those associated with chronic bronchitis, particularly in children and asthmatics;

increased work loss days and school absences;

changes to lung structure and natural defense mechanisms.

Based on review of the scientific data, during the 1997 NAAQS review process nineteen of twenty-one CASAC panel members recommended revising the then-current PM_{10} standards by adding standards for fine particles. CASAC unanimously recommended retaining at least one or more PM_{10} standards.

A great deal of PM-related research has been conducted, yet I would not be a scientist if I did not point out that there also are uncertainties. We expect these uncertainties. I was asked, last summer, "Aren't you disturbed by these uncertainties and the research that is available for particulate matter?" I responded that, as a scientist, I am accustomed to uncertainties. It is what we expect. The evaluation of those uncertainties requires a judgment call. We look to CASAC to

4. "Fine" particles are those which pass through a size selective inlet with a 50% cutoff at 2.5 um aerodynamic diameter.

5. "Course" particles are those which pass through a size selective inlet with a 50% cutoff at 10 um aerodynamic diameter, less the $PM_{2.5}$ mass fraction.

help ensure that the judgment regarding what the standard should be is based on the best available science, but the judgment itself is made in the face of uncertainty.

Given the 1997 NAAQS decisions,[6] where do we go from here? At this time the scientific community is conducting many studies to improve the scientific data for future standards review and implementation. For the next PM review we are on a time line in which we need to have studies completed and accepted for publication in the peer reviewed literature by early in the year 2000. Research, however, takes time. Typically, several years may elapse from the initiation of a study to the publication of results. To ensure that the highest priority needs are targeted with resources, we need to employ an extensive research planning process. Simply put, the research needs (represented by the dashed lines in Figure 2) are evaluated to identify the most significant data gaps and priorities. The priorities are compared with the current and planned inventory of research activities underway in the scientific community, at EPA and at other research organizations. Workshops and extensive engagement of the scientific community help to develop a consensus about what the current and future research directions and priorities should be. Based on this process, EPA and other organizations allocate their resources accordingly, and the scientific data generation and review process cycles again, as indicated in Figure 2.

In consultation with the scientific community, EPA has developed the following list of some priority needs for particulate matter to develop a better understanding of these important areas:

elucidate causal biological mechanisms;
identify factors affecting susceptibility;
characterize key components producing toxicity;
characterize effects of long-term exposure;
develop exposure-dose-response relationships;

6. *See* National Ambient Air Quality Standards for Particulate Matter, 40 C.F.R. pt. 50 (1997).

understand exposure relationships (central monitors versus actual human exposures);
develop improved measurement methods;
develop atmospheric chemistry and models;
characterize emissions.

This is both a short list, and a tall order. In recognizing the importance of improving and expanding the evidence available for the next round of the PM criteria document development and NAAQS review, President Clinton wrote:

> The EPA, in partnership with other Federal agencies, will develop a greatly expanded coordinated interagency PM research program. The program will contribute to expanding the science associated with particulate matter health effects, as well as developing improved monitoring methods and cost-effective mitigation strategies.[7]

EPA has taken on this charge and is looking at both the public and private sectors to develop a research program to address the priority scientific questions. The point here is that it is not just EPA that is performing research to address the priority research needs. At EPA we have a vigorous research program. We are extensively coordinating our research program with other agencies, including the Department of Health and Services, the Health Effects Institute (which represents a public/private partnership focused on health and exposure issues), the North American Research Strategy for Tropospheric Ozone (NARSTO, another public/private research partnership focused on atmospheric sciences issues) and others. This ensures that your tax dollars are spent in the most efficient and effective manner.

To summarize, I believe the evidence available today shows that ozone and particulate matter present in ambient air are associated with significant health effects. There are uncertainties in the science, and various scientists may offer differing interpretations of the available data and the signifi-

7. Implementation Plan for Revised Air Quality Standards for Ozone and Particulate Matter attached to memorandum from President Clinton to Carol Browner, EPA Administrator (July 16, 1997) (on file with speaker).

cance of the uncertainties. Scientists generally accept that uncertainties exist. These uncertainties present research challenges that we are trying to address. We are looking beyond the public agencies, to partners in the private sector and public/private partnerships, to ensure the coordination of research and to ensure that the uncertainties are addressed in a timely fashion.

In the future, I believe we will reap significant benefits from the research and regulatory review process. As time passes, I think that we will have new methods, models and data needed to make ever more confident risk management decisions. In addition, I expect increasing recognition of the combined influence of ozone, particulate matter, sulfur oxide, nitrogen oxide and hazardous air pollutants on health outcomes. In other words, I believe we will move, at least in the research context, toward studies of the real atmospheres to which people are exposed. Since we are exposed to a mixture of pollutants in our daily lives, we need to evaluate the potential synergistic or antagonistic effects of pollutants in combination on health. This, to me, is an important future direction for our research programs.