

CRS Report for Congress

Received through the CRS Web

Particulate Matter Air Quality Standards: Background and Current Developments

Updated January 10, 2005

Robert Esworthy
Specialist in Environmental Policy
Resources, Science, and Industry Division

Particulate Matter Air Quality Standards: Background and Current Developments

Summary

The Environmental Protection Agency (EPA) is nearing completion of its review of contentious air quality standards for particulate matter (PM), with final action expected in late 2005. The current standards are among the most far-reaching regulations on EPA's agenda. Promulgated in 1997, but only now being implemented, the standards could potentially prevent the loss of thousands of lives annually at an annual cost estimated by the agency to be \$8.6 billion.

The Clean Air Act (CAA, Sections 108 and 109) requires that air quality criteria used in determining National Ambient Air Quality Standards (NAAQS) reflect the latest scientific information. The act includes provisions for the periodic review and revision, as appropriate, of existing criteria and standards. It is this periodic review process that is nearing completion. In October 2004, EPA released *Air Quality Criteria for Particulate Matter*, reflecting the agency's synthesis of relevant PM research conducted since the agency's last review, completed in 1996. This report, referred to as a "criteria document," will provide the scientific basis for assessments and policy decisions regarding the adequacy of the current PM NAAQS. Further decisions, including recommendations regarding the standards, are expected early in 2005, following the release of what is referred to as a "staff paper."

Meanwhile, EPA is continuing implementation of the 1997 particulate matter standards, which had been delayed several years by litigation and other factors. On January 5, 2005, EPA published the final designations of geographical areas for the fine particulate matter or "PM_{2.5}" (particles less than 2.5 micrometers in diameter) NAAQS. EPA designated 225 counties in 20 states, and the District of Columbia, as "nonattainment areas"; those areas with (or contributing to) air quality levels exceeding the annual and 24-hour PM_{2.5} standards.

Congress and a wide variety of stakeholders have closely followed the evolution and development of PM NAAQS. In 1997, when the current standards were promulgated, Congress held 28 days of hearings on the EPA rule. Subsequently, more than 100 plaintiffs sued to overturn the standards. This litigation went to the Supreme Court before being resolved, largely in EPA's favor, in February 2001.

Since FY1998, in an effort to expedite research and strengthen the science underlying EPA's review of the standards, Congress has appropriated funding specifically for PM research annually (\$62 million for FY2005). The research, including re-analysis of key studies underlying the 1997 standards, has largely confirmed EPA's earlier conclusions, although new questions have been raised regarding the methodology used in some of the studies. The National Academy of Sciences (NAS) has issued four reports on the state of PM research at EPA, and EPA released a report reviewing its five-year progress of PM research.

Because of the potential impacts particulate matter standards could have on both public health and the economy, EPA's reassessment of the PM standards will likely be of continued interest to Congress. This report will be updated as events warrant.

Contents

Introduction	1
Recent Developments	2
Review of Particulate Matter Scientific Data	2
Implementation of Current (1997) PM NAAQS	2
Overview	3
Process for Setting National Ambient Air Quality Standards	4
History of Particulate Matter Standards	6
1997 Ozone NAAQS	8
Legal Challenges to the 1997 PM NAAQS	9
Court of Appeals	9
Supreme Court	11
On Remand to the Court of Appeals	11
Health Effects of Particulate Matter	12
Science Behind the 1997 PM NAAQS	12
Particulate Matter Scientific Knowledge Since 1997	14
Increased Particulate Matter Research Funding	14
National Academy of Science (NAS) Particulate Matter Research Priorities	15
HEI-Sponsored National Morbidity Mortality and Air Pollution Studies	17
Re-analyses of Selected Time-Series Studies	20
Status of EPA's Review of the 1997 PM NAAQS	20
Schedule	21
2004 Particulate Matter Criteria Document	21
EPA Particulate Matter Staff Paper	23
Opposing Views, Potential Challenges and Litigation	24
Implementation of the 1997 PM NAAQS	26
PM _{2.5} Monitoring Network	26
PM _{2.5} Attainment/Nonattainment Geographical Designation	27
Other Activities Impacting PM NAAQS Implementation	28
Current CAA Regulation	28
Proposed Regulations and Legislation	29
California Particulate Matter Standards	29
International Particulate Matter Standards	30
Conclusions	32

List of Tables

Table 1. Changes to Particulate Matter National Ambient Air Quality Standards (NAAQS)	7
Table 2. Research Priorities for Particulate Matter Identified by the National Academy of Sciences	16
Table 3. California's State Particulate Matter Standards and the 1997 National Primary Particulate Matter Standards	30
Table 4. PM ₁₀ and PM _{2.5} Air Quality Standard Comparison of United States and Selected Countries	31

Particulate Matter Air Quality Standards: Background and Current Developments

Introduction

Under the Clean Air Act (CAA), EPA is responsible for protecting public health and the environment from emissions that pollute ambient, or outdoor, air. Under Sections 108-109 of the CAA, Congress mandated that EPA set national ambient air quality standards (NAAQS) for pollutants whose emissions “may reasonably be anticipated to endanger public health or welfare” and “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources” (42 U.S.C. 7408(a)(1)).

EPA has identified and promulgated NAAQS for six principal pollutants classified by the agency as “criteria pollutants”: particulate matter (PM), ozone (O₃, a key measure of smog), nitrogen dioxide (NO₂, or, inclusively, nitrogen oxides,¹ NO_x), sulfur oxides (SO_x, or, specifically, SO₂), carbon monoxide (CO), and lead (Pb). Every five years, according to the statute (but less frequently in practice), EPA is required to review the latest scientific studies and either reaffirm or modify the NAAQS. The most recent changes, a strengthening of the particulate matter and ozone standards, were promulgated jointly in 1997.

Since they were modified in 1997, the particulate matter standards (also referred to as the PM NAAQS) issued by EPA,² and the subsequent review to evaluate whether to revise these standards again, have been the source of significant controversy. The particulate matter standards have prompted a national debate regarding how much scientific information is necessary before a regulation can be put in place, and the appropriate levels of health protection. Congress has been especially interested in EPA’s promulgation of these CAA standards and has held numerous hearings on particulate matter.

As required by the CAA, EPA has been reviewing the current particulate matter standards. The agency recently finalized its review of the scientific research completed since 1996 and is expected to complete its determination of whether to increase or decrease the stringency of the standard, or reaffirm the current standards, by late 2005 or early 2006.

¹ The NAAQS is for NO₂; nitrogen gases that are ozone precursors are referred to as NO_x.

² The original PM NAAQS were for “Total Suspended Particulates” (TSP). In 1987, the standards focused on particles smaller than 10 microns (PM₁₀). In 1997 EPA added standards for “fine” particles smaller than 2.5 microns (PM_{2.5}), for the first time. EPA also revised the existing NAAQS for PM₁₀ (61 *Federal Register* 38652-38896, December 13, 1996). See discussion later in this report.

This report is intended to assist the reader in understanding the history of the particulate matter standards.³ Following a brief summary of recent developments regarding the implementation and re-evaluation of the 1997 standards, the report provides a broad overview of the standard-setting process, followed by a description of revisions to earlier standards, legal challenges to the 1997 standard, and particulate matter health effects research. EPA's ongoing progress in reviewing the 1997 standard is then summarized. Other activities that potentially impact the implementation and review of the particulate matter standards, such as other air quality regulations and proposed legislation, are also discussed in this report.

Recent Developments

Review of Particulate Matter Scientific Data. In October 2004, EPA released *Air Quality Criteria for Particulate Matter*. Referred to as a "criteria document," the report has undergone extensive peer review and comment, and presents the results of the EPA's review of numerous studies and related research compiled since the agency completed its previous review in 1996. The information in the report will serve as the scientific basis for further assessment by EPA technical staff in developing options to be considered regarding policy decisions affecting the adequacy of the current PM NAAQS promulgated in 1997. The ultimate determination by the EPA Administrator of whether to change the existing PM NAAQS is not expected until late 2005 or early 2006.

Implementation of Current (1997) PM NAAQS. EPA recently completed the process for designating geographical areas as attainment or nonattainment with respect to the current particulate matter air quality standard. The EPA Administrator signed a final rule on December 17, 2004, designating of all or part of 225 counties⁴ in 20 states, as well as the District of Columbia, for nonattainment of the NAAQS for fine particulate matter or "PM_{2.5}" (particles less than 2.5 micrometers (μm) in diameter). The final rule was published in the *Federal Register* on January 5, 2005 (70 *Fed. Reg.* 944-1019), and goes into effect April 5, 2005 (90 days from the date of publication).

Nonattainment designation begins a process in which states (and tribes) must develop and adopt emission control programs sufficient to bring air quality into compliance by an EPA-defined deadline. States are required to submit "implementation" plans for how they will meet the PM_{2.5} NAAQS by early 2008, and must be in compliance by 2010 unless they are granted a five-year extension. For a more detailed discussion of the implementation of the 1997 PM NAAQS, and the associated designation process, see CRS Report RL32431, *Particulate Matter (PM_{2.5}): National Ambient Air Quality Standards (NAAQS) Implementation*.

³ Given the historical nature of the report, portions of the discussion are unchanged from an August 6, 2002, report under the same title, prepared by Anne L. Hardenberg, formerly of the Congressional Research Service, Resources, Science, and Industry Division.

⁴ Includes 7 cities: Baltimore, MD; St. Louis, MO; Alexandria, VA; Fairfax, VA; Falls Church, VA; Manassas, VA; and Manassas Park, VA.

Overview

Similar to the review that led to the establishment of the existing PM NAAQS in 1997, EPA's current review of the national particulate matter standards is expected to be controversial. Both the health effects of particulate matter and the economic effects associated with particulate matter control are potentially significant.

On the one hand, large concentrations of particulate matter have been known to cause deaths, most infamously in London's "Killer Fog," which killed as many as 4,000 people in December 1952. Smaller concentrations of particulate matter have also been linked to health effects, particularly for sensitive populations, such as children, asthmatics, and the elderly. Stricter controls on particulate matter should mean fewer health effects.

In issuing its 1997 NAAQS for particulate matter which included a standard for fine particles (PM_{2.5}) for the first time, EPA projected that attaining the new standard for PM_{2.5} would annually reduce deaths in Los Angeles County by approximately 280 and reduce cases of respiratory symptoms by roughly 20,000.⁵ For Philadelphia County, an area with relatively cleaner air, attaining the 1997 PM_{2.5} standard was estimated to reduce deaths by 40 and cases of respiratory symptoms by 1,000 each year.⁶ Overall, EPA estimated that partial attainment of the 1997 PM_{2.5} standard would annually result in the avoidance of 3,300 to 15,600 incidences of premature mortality nationwide.⁷

The 1997 PM NAAQS and the supporting scientific data generated significant scrutiny and controversy, and were the subject of multiple lawsuits. Various stakeholders disagreed on whether the standards were too strong or too weak. Although the standards were upheld in litigation, EPA, Congress, the Clean Air Scientific Advisory Committee mandated by the 1977 CAA Amendments, and other scientific groups recognized the need to enhance the scientific basis for the PM NAAQS. The resulting coordinated research effort has advanced the understanding of the potential health effects associated with particulate matter, but critical information gaps continue.

Achieving the PM NAAQS will entail costs. In particular, some of the areas expected to be out of compliance with the 1997 PM_{2.5} standards have not previously been designated nonattainment for any other NAAQS. Many large industries, such as utilities, refineries, and the trucking industry, are concerned that they likely will be affected by the necessary controls on particulate matter emissions to achieve compliance. Stricter controls on particulate matter will likely mean more costs for

⁵ 61 *Federal Register* 65651, December 13, 1996.

⁶ 61 *Federal Register* 65651, December 13, 1996.

⁷ EPA, *Regulatory Impact Analysis for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule*, July 1997, p. ES-18. Available at [<http://www.epa.gov/ttn/oarpg/naaqsf/ria.html>].

affected industries. EPA estimated the costs to partially attain the 1997 PM_{2.5} standard by 2010 at \$8.6 billion annually,⁸ while industry estimates were several times higher.

Another concern of areas facing nonattainment designation, particularly of local businesses and governments, is that it will have potential negative impacts on an area's economic development. Nonattainment designation requires new major sources of pollution to offset their pollution by equivalent, or greater, emission reductions from existing sources, and requires highway and transit planners to demonstrate that new projects "conform" to the area's state implementation plans. Although EPA has not analyzed the potential economic impact of designating areas as nonattainment for particulate matter, a recent EPA analysis found that ozone nonattainment designations had no net negative impact on those areas.⁹

Due to the significance of these issues, Congress is likely to remain interested in the outcome of EPA's ongoing implementation and review of the existing PM NAAQS.

Process for Setting National Ambient Air Quality Standards¹⁰

The first step in regulating criteria pollutants is the issuance of what is known as a "criteria document." This document must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air" (42 U.S.C. 7408(a)(2)). Included in this document is information on "variable factors" that change public health effects, other types of pollutants that may interact with the criteria pollutants to adversely affect public health, and "known or anticipated adverse effects on welfare" (42 U.S.C. 7408(a)(2)(A-C)).

Subsequent to the preparation of the criteria document, EPA has inserted an administrative step into the process known as the "staff paper." The staff paper, compiled by EPA technical staff, provides the Administrator with a report that describes the policy implications of the criteria document and provides recommendations based on these implications. Emphasis is placed on "identifying those conclusions and uncertainties in the available scientific literature that the staff believes should be considered in selecting particulate pollutant indicators, forms, averaging times, and levels for the primary (health) and secondary (welfare) standards" (EPA, *Particulate Matter Staff Paper* (1996), p. I-1).

Both the staff paper and the criteria document are reviewed by the Clean Air Scientific Advisory Committee (CASAC). This committee, mandated under Section 109(d)(2) of the CAA, consists of seven outside experts who recommend revisions to the documents and comment on the desirability of new standards, as appropriate.

⁸ EPA, *Regulatory Impact Analysis*, July 1997, Table 13-1.

⁹ U.S. EPA, Office of Air and Radiation, *The Historical Record: Nonattainment Status and Economic Growth*, February 26, 2002.

¹⁰ For more information on the standard-setting process, see CRS Report 97-722 ENR, *Air Quality Standards: The Decisionmaking Process*.

The CASAC creates a panel to review each NAAQS. Each panel consists of the members of the CASAC plus consultant members to assure full coverage of the expertise needed to assess fully the issues involved. The panel recommends improvements and eventually, after further meetings that are open to the public and reviews, signs off only when they are convinced that each of the two documents accurately reflects the status of the science. The CASAC “closure letter” represents panel members’ agreement that the criteria document and the staff paper provide an adequate scientific basis for regulatory decision making.

With the release of the criteria document and the staff paper, EPA is to issue proposed standards to control the criteria pollutant. These standards are known as primary and secondary national ambient air quality standards (NAAQS). Primary NAAQS are set at a level “requisite to protect the public health” with an “adequate margin of safety” (42 U.S.C. 7409(b)(1)). Secondary NAAQS are set at a level “requisite to protect the public welfare” (42 U.S.C. 7409(b)(2)).¹¹ Secondary standards are implemented in the same manner as primary NAAQS, with the key difference that there is no federally enforceable specified deadline for attainment.

After EPA promulgates a nationwide standard for a criteria pollutant, the agency is to designate geographical areas as in “attainment” or “nonattainment” with the standards through a federal-states/tribes cooperative process. Areas are to be identified as “nonattainment” when they violate or contribute to the violation of National Ambient Air Quality Standards (NAAQS), or “attainment/unclassified” when they meet the standard or the data are insufficient for making a determination of compliance with the NAAQS. Nonattainment designation begins a process in which states (and tribes) must develop and adopt emission control programs sufficient to bring air quality into compliance by an EPA-defined deadline (statutory for the primary standards).

Following designation of an area as nonattainment, the state where the area is located must develop a State Implementation Plan (SIP) that demonstrates how attainment with the NAAQS will be achieved, and submit it to the EPA within three years of designation (Section 110 of the CAA). These plans must include, among other items, emissions limitations, monitoring provisions, and enforcement programs designed to achieve compliance with the standard, generally within a 10-year period. Thus, under the statute, EPA sets only the nationwide standard for criteria pollutants; the states are responsible for placing limits on emissions that contribute to criteria pollution and for regulating entities emitting criteria pollutants. (If states fail to develop an adequate implementation plan, EPA can impose one).

Reviews and updates of the criteria document are to take place at least every five years and standards may be modified on the basis of new information identified and evaluated during the update of the criteria document.

¹¹ The use of public welfare in the CAA “includes, but is not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants” (42 U.S.C. 7602(h)).

History of Particulate Matter Standards

EPA set the first particulate matter standards in 1971. The first standards were based on total suspended particulate matter (TSP). Monitors for TSP detected particles up to 45 micrometers (μm) in diameter. There were two forms to the primary standards: 24-hour (daily) average and annual geometric mean. The primary standards were set at a 24-hour average not to exceed 260 micrograms of particulate matter per cubic meter of air ($\mu\text{g}/\text{m}^3$) more than once per year, and an annual geometric mean of $75 \mu\text{g}/\text{m}^3$. The secondary standards were set only in the 24-hour form at $150 \mu\text{g}/\text{m}^3$, not to be exceeded more than once per year.

EPA began revising the criteria document for the PM NAAQS in 1979. Three draft criteria documents were prepared, comments were received, and several public meetings were held. In 1984, EPA issued its final criteria document and proposed changes to the 1971 standards. These changes were finalized in 1987. Because research indicated that health effects were associated with smaller particles, the indicator for particulate matter was changed from TSP to particles with a diameter of $10 \mu\text{m}$ or less in 1987. These particles are generally denoted PM_{10} . The form of the annual standard was changed from annual geometric mean to annual arithmetic mean.¹² Primary NAAQS for PM_{10} were set at a 24-hour average of $150 \mu\text{g}/\text{m}^3$, with no more than one expected exceedance averaged over three years, and an annual arithmetic mean of $50 \mu\text{g}/\text{m}^3$ averaged over three years. Secondary NAAQS were set at levels identical to primary NAAQS.

EPA's announcement of the next round of revisions to the particulate matter criteria document came in 1994. After drafts of both the criteria document and staff paper were provided for public comment, EPA issued proposed changes to the 1987 standards in November 1996. During the comment period for the proposed changes, EPA held four public hearings at locations across the nation, in addition to two satellite broadcasts. EPA also developed a toll-free national hotline and an e-mail address to facilitate participation by interested persons. EPA notes that it received more than 14,000 calls and 4,000 e-mails in response to the proposed changes, with a total of over 50,000 comments.

Final NAAQS from this second round of revisions were issued July 18, 1997, as per a court order.¹³ In these new standards EPA added the indicator $\text{PM}_{2.5}$, because of new data showing significant public health effects from fine particles. This indicator regulates particles with a diameter less than $2.5 \mu\text{m}$, also known as "fine particles." EPA retained the PM_{10} indicator to regulate "coarse" particles.

¹² According to EPA, the annual geometric mean was replaced because it was greatly influenced by days of relatively clean air and de-emphasized the effects of short-term peak concentrations. EPA indicated that the annual arithmetic mean did a better job of addressing these problems. See 52 *Federal Register* 24640. July 1, 1987.

¹³ EPA was under a court order entered in *American Lung Association v. Browner*, CIV-93-643-TUC-ACM (D. Ariz., October 6, 1994) to publish the final PM standards by July 19, 1997.

The form of the 24-hour standards was also changed in 1997. The previous form was known as the “one-expected-exceedance” form; monitoring stations could exceed the 24-hour PM NAAQS only once, averaged over three years. With the 1997 final rule, EPA changed to a concentration-based percentile form. This percentile form indicates the percent of the time that a monitoring station can exceed the standard. For instance, a 99th percentile 24-hour standard indicates that a monitoring station can exceed the standard 1% of the time, or 3.65 days a year, if monitoring occurs every day. The form of the annual standard remained the same in the 1997 revisions.

Finally, EPA revised the levels of the PM NAAQS. The new PM_{2.5} indicator was set at 65 µg/m³, based on a three-year average of the 98th percentile of 24-hour PM_{2.5} concentrations, and at 15 µg/m³ for the annual arithmetic mean averaged over three years. The levels of PM₁₀ remained the same; however, the form of the PM₁₀ 24-hour standard was changed to be based on a three-year average of the 99th percentile of 24-hour PM₁₀ concentrations. By changing the form to a concentration-based percentile, EPA allowed more exceedances than were previously permitted under the 1987 standard. Thus, although the level of the PM₁₀ standards was not changed, the change in form had the effect of weakening the PM₁₀ standard by allowing more exceedances. Nonetheless, the new PM_{2.5} standards would require additional controls. Secondary standards were set equal to these new primary NAAQS. The changes to the PM NAAQS are summarized in **Table 1**.

Table 1. Changes to Particulate Matter National Ambient Air Quality Standards (NAAQS)

	1971	1987	1997
Indicator	<i>Total Suspended Particulate Matter</i>	<i>PM₁₀</i>	<i>PM₁₀ and PM_{2.5}</i>
Form	24-hour average (not to be exceeded more than once per year) Annual geometric mean	24-hour average (1-expected-exceedance, 3-year average) Annual arithmetic mean	24-hour average (concentration-based percentile) Annual arithmetic mean
24-hour Primary NAAQS	260 µg/m ³	150 µg/m ³	PM ₁₀ : 150 µg/m ³ (99 th percentile) PM _{2.5} : 65 µg/m ³ (98 th percentile)
Annual Primary NAAQS	75 µg/m ³	50 µg/m ³	PM ₁₀ : 50 µg/m ³ PM _{2.5} : 15 µg/m ³
Level of Secondary NAAQS	150 µg/m ³ 24-hour standard	Same as primary	Same as primary

Source: Prepared by the Congressional Research Service.

As proposed, the new PM NAAQS generated significant controversy.¹⁴ Once finalized, the standards were subject to lawsuits from a number of parties, some seeking a stronger standard, others seeking a weaker standard.

1997 Ozone NAAQS. The final PM NAAQS were signed by the EPA Administrator at the same time as new NAAQS for ground-level ozone, on July 16, 1997. The two NAAQS were jointly published on July 18, 1997 (62 *Federal Register* 38652-38896). Generally referred to as the 8-hour ozone standard, the new standard for ground-level ozone requires a more stringent concentration limit (0.08 parts per million vs. the previous 0.12), but it averages the ozone concentrations measured over 8 hours rather than the previous 1 hour. (See CRS Report RL32345, *Implementation of EPA's 8-Hour Ozone Standard.*)

Ozone is not a pollutant that is directly emitted; rather it forms in the atmosphere in the presence of sunlight, primarily as the result of reactions including volatile organic compounds (VOCs). Nitrogen oxides (NO_x) are considered PM_{2.5}, as well as ozone precursors. Thus, the emitters of NO_x, such as various industrial processes, motor vehicles, and other fuel combustion sources, will be subject to controls for purposes of meeting two different NAAQS. In addition, many of the areas designated nonattainment with respect to the 8-hour ozone standards are expected to overlap with those designated nonattainment for the PM NAAQS. In its PM_{2.5} guidance for geographical area designation, EPA recommended states consider using the same boundaries for nonattainment for both PM_{2.5} and 8-hour ozone.

Implementation of the 8-hour ozone standard, which currently precedes the PM NAAQS implementation, as well as challenges or other delays, will likely impact the implementation, and potentially the review of the PM NAAQS. Following their joint promulgation in 1997, both the ozone and the PM NAAQS were the subject of many of the same challenges and litigation, including a Supreme Court decision in 2001 (see discussion later in this report).

On April 15, 2004, EPA designated areas in 32 states and the District of Columbia (474 counties in all) as “nonattainment areas” for the new ozone air quality standard (69 *Federal Register* 23857-23951). The EPA designations, and the new implementation rule (69 *Federal Register* 23951-24000) that accompanied the designations, have been challenged for being too lenient by several states and various public interest groups, and too restrictive by industry groups. Since June of 2004, several petitions for reconsideration¹⁵ have been submitted to EPA, and 17 challenges have been filed in the U.S. Court of Appeals for the District of Columbia Circuit (as of December 2004). Based on an unopposed motion filed by EPA November 24, 2004, the cases have been aligned by the issues into two consolidations (*South Coast Air Quality Management District v. EPA*, No. 04-1200 (D.C. Cir. filed 6/25/04), and *Alcoa Inc. v. EPA*, No. 04-1189 (D.C. Cir. filed 6/18/04)). The outcome of these

¹⁴ For more information on Congressional hearings related to the proposed standards and issues related to implementation of the standard, see CRS Report 97-8 ENR, *Air Quality: Background Analysis of EPA's 1997 Ozone and Particulate Matter Standards*, pp. 27-31.

¹⁵ For information regarding the petitions for reconsideration see EPA's Office of Air and Radiation website at [<http://www.epa.gov/ttn/naaqs/ozone/o3imp8hr/whatsnew.html>].

challenges, and their potential impact on the PM NAAQS implementation and review, may not be known for some time.

Legal Challenges to the 1997 PM NAAQS

Court of Appeals. On July 18, 1997, the day of promulgation for the final PM NAAQS (and new 8-hour ozone standard), the American Trucking Associations (ATA), together with five other groups, filed a suit against the EPA. Several other groups also challenged EPA's PM NAAQS in court, including states, industries, small businesses, environmental groups, and private persons. In all, more than 100 petitioners challenged EPA's PM NAAQS, including three states and over 60 utilities; six states filed briefs in support of EPA. These plaintiffs filed a total of 38 cases against EPA; the cases were consolidated by the U.S. Court of Appeals for the District of Columbia Circuit.¹⁶

The plaintiffs advanced ten arguments against EPA's 1997 revisions to the particulate matter standards. Various plaintiffs claimed that EPA:

- Unconstitutionally interpreted §§ 108 and 109 of the CAA;
- Arbitrarily and capriciously chose PM₁₀ as the coarse particle indicator;
- Must consider costs in setting NAAQS;
- Must consider the financial impact of complying with the NAAQS on the Abandoned Mine Reclamation Fund;
- Must treat PM_{2.5} as a "new" pollutant and develop a separate criteria document;
- Must identify a biological mechanism through which particulate matter causes health effects;
- Must set secondary PM NAAQS such that all visibility impairment is eliminated;
- Failed to comply with relevant requirements of the National Environmental Policy Act;
- Violated the Unfunded Mandates Reform Act in revising PM NAAQS by not preparing an official Regulatory Impact Statement; and
- Violated the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act, in revising PM NAAQS by not performing a regulatory flexibility analysis to determine the impact of the NAAQS on small entities.

The Court of Appeals rejected the last eight claims of the petitioners. On the first claim, the Court noted that EPA's construction of the NAAQS section of the CAA allowed the agency to set NAAQS at "any point between zero and a hair below

¹⁶ *American Trucking Associations v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999). The challenges to the PM standards were also consolidated with challenges made to EPA's ozone standards released the same day.

the concentrations yielding London's Killer Fog."¹⁷ The court ruled that the statutory language was an unconstitutional delegation of legislative power. However, rather than hold these sections of the CAA unconstitutional, the Court of Appeals decided to "give the agency an opportunity to extract a determinate standard on its own."¹⁸ In its decision, the Court of Appeals presented some options for the "intelligible principle" EPA might use to develop a constitutional interpretation of the act.

As to the second claim, the Court of Appeals agreed that EPA's use of PM₁₀ as the coarse particle indicator was arbitrary and capricious. PM₁₀ includes all particles smaller than 10 µm. Because EPA had also chosen PM_{2.5} as an indicator of fine particulate matter, the choice of PM₁₀ constituted a "double regulation" of PM_{2.5} and an "underregulation" of PM_{10-2.5}, that is, particles between 2.5 and 10 µm in diameter.¹⁹ The Court of Appeals vacated the PM₁₀ standard and directed EPA to select a different indicator.

The challenge to the science behind the PM NAAQS — the claim that EPA had to identify a biological mechanism — was unsuccessful before this court. The petitioners had argued that EPA had to prove that particulate matter caused health effects before issuing standards, and that there was no scientific basis to regulate coarse particulate matter. Although the Court of Appeals found that EPA's retention of PM₁₀ as an indicator was arbitrary and capricious, the court found "ample support for EPA's decision to regulate coarse particulate pollution above the 1987 levels."²⁰

The Court of Appeals' decision was 2-1, with the dissenter arguing that Sections 108 and 109 did not effect an unconstitutional delegation of legislative power and therefore did not violate the nondelegation doctrine.²¹ For invoking the nondelegation doctrine, the decision was variously seen as "[giving] a warning to overzealous regulators,"²² "[lobbying] a constitutional time bomb that potentially could have governmentwide impact,"²³ and as "[defying] 60 years of Supreme Court rulings."²⁴ EPA's then-Administrator, Carol Browner, called the ruling "extreme, illogical, and

¹⁷ 175 F.3d at 1037.

¹⁸ 175 F.3d at 1038.

¹⁹ 175 F.3d at 1054.

²⁰ 175 F.3d at 1054.

²¹ 175 F.3d at 1057 (Tatel, dissenting).

²² Lieberman, Ben. "Clearing the Air on Regulatory Excess." *The Washington Times* 19 May 1999: A16.

²³ May, Randolph J. "D.C. Circuit Decision Draws Needed Spotlight to Nondelegation Doctrine." *Legal Times* 21 Jun. 1999: 20.

²⁴ Lieberman, Joseph I. and Henry Waxman. "A New Arena for Attacks on Clean Air: The Courts." *The Hartford Courant* 10 Sept. 1999: A23.

bizarre.”²⁵ In contrast, the U.S. Chamber of Commerce stated “this ruling strikes right at the heart of EPA’s abuse of regulatory authority.”²⁶

Supreme Court. EPA sought to have the Court of Appeals rehear the case, but was denied. EPA then appealed the ruling to the Supreme Court. EPA sought the Court’s opinion on whether the CAA impermissibly delegates legislative power to the agency.²⁷ ATA and other groups also appealed the decision and asked the Supreme Court to review the question of whether EPA must take the cost of the standards into account when setting NAAQS. The Supreme Court consolidated the cases and issued its decision on February 27, 2001.²⁸

On the two principal issues (whether EPA was unconstitutionally exercising legislative power, and whether costs should be considered in setting NAAQS), the Supreme Court ruled in EPA’s favor. Justice Scalia wrote the unanimous opinion of the Court, and some Justices added separate concurring opinions. The Court affirmed the judgment of the Court of Appeals regarding cost consideration in setting NAAQS: “the text of 109(b) ... unambiguously bars cost considerations from the NAAQS-setting process.”²⁹ The Court overturned the judgment of the Court of Appeals regarding the nondelegation doctrine, stating “Section 109(b)(1) ... fits comfortably within the scope of discretion permitted by our precedent.”³⁰ The Court stated that the provision contains an “intelligible principle” to guide the Administrator in setting standards, and that is all that is constitutionally required.

On Remand to the Court of Appeals. In the original case, the petitioners had raised other challenges to the standards that the Court of Appeals stated “cannot be resolved until such time as EPA may develop a constitutional construction of the act.”³¹ Because the Supreme Court subsequently ruled that Sections 108 and 109 were constitutional in respect to delegation, the Court remanded the case to the Court of Appeals for consideration of petitioners’ arguments raised under CAA §307(d)(9).³² The question facing the Court of Appeals was whether EPA reasonably exercised its discretion under the CAA in establishing PM_{2.5} NAAQS (the PM₁₀ standard was vacated in the earlier decision).³³ The plaintiffs in this case advanced nine arguments against EPA’s rulemaking. Various plaintiffs claimed that EPA:

²⁵ Kennedy, James. “Court Decision on Ozone, PM Rules Called ‘Extreme, Illogical’ by Browner.” *Daily Environment Report* 21 May 1999: AA-1.

²⁶ Kennedy, James. “EPA Eyes Appeal of PM-Ozone Ruling, Says Ruling Supportive of Science, Process.” *Daily Environment Report* 17 May 1999.

²⁷ EPA also sought the Supreme Court’s opinion on two ozone questions unrelated to the PM discussion in this report.

²⁸ *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

²⁹ 531 U.S. at 471.

³⁰ 531 U.S. at 476.

³¹ *ATA v. EPA*, 175 F.3d at 1034.

³² *American Trucking Associations v. EPA*, 283 F.3d 355 (D.C. Cir 2002).

³³ 283 F.3d at 363-364.

- Did not identify or apply any legal standard in setting NAAQS;
- Did not show the 1987 PM standards to be inadequate to protect public health;
- Attributed adverse health effects to PM that are accounted for by other factors, such as the presence of other pollutants, temperature, and humidity;
- Conceded that NAAQS rely on questionable assumptions, such as the existence of a “continuum of health risks”;
- Failed to justify the 24-hour standard;
- Did not present enough evidence in the rulemaking record to support the level of the annual standard;
- Must obtain and publish underlying data from studies it uses in rulemaking;
- Should have set a stricter daily standard; and
- Set secondary standards that were inadequate to improve visibility.

The Court of Appeals rejected all these claims with the exception of the fifth claim (failure to justify the 24-hour standard), which it declined to consider because the claim was not raised in the original case.³⁴ The effect of these cases has been to demonstrate that EPA does have authority to promulgate NAAQS, that cost cannot be considered in setting the NAAQS, that EPA’s revision of the PM NAAQS was not arbitrary and capricious, and that stricter regulation of particulate matter was supported by the record, although selection of PM₁₀ as the coarse particle indicator was arbitrary and capricious.

Health Effects of Particulate Matter

Science Behind the 1997 PM NAAQS. EPA began its review of the relevant scientific literature in 1994 to determine what studies to include in the criteria document. The studies selected were peer-reviewed, mainly by non-EPA researchers. In researching particulate matter health effects, EPA reviewed more than 2,000 studies. In the criteria document, EPA noted, “recent studies [provide] evidence that serious health effects (mortality, exacerbation of chronic disease, increased hospital admissions, etc.) are associated with exposures to ambient levels of particulate matter found in contemporary U.S. urban air sheds even at concentrations below current U.S. PM standards.”³⁵

The reviewed studies, taken as a whole, revealed significant health effects from particulate matter. Health effects EPA found to be associated with particulate matter include:

³⁴ 283 F.3d at 358, 371.

³⁵ EPA, *Air Quality Criteria for Particulate Matter*, April 1996, EPA/600/P-95-001aF. p. 13-1, at [http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_pr_cd.html].

- Premature mortality from short-term exposure (based on 38 analyses and re-analyses of studies published between 1988 and 1996),³⁶ and long-term exposure (based on studies from the 1987 revision and 2 new studies);³⁷
- Aggravation of respiratory and cardiovascular disease from short-term exposure (based on 12 studies);³⁸
- Changes in lung function and increased respiratory symptoms (based on 26 short-term and 7 long-term studies);³⁹
- Changes to lung tissues and structure (based on studies from the 1987 revision);⁴⁰ and
- Altered respiratory defense mechanisms (based on studies from the 1987 revision).⁴¹

Of the epidemiological studies EPA reviewed, more than 80 of them addressed particulate matter's association with morbidity and mortality based on short-term exposures. Of these 80, 60 studies found statistically significant associations between increases in various indicators of particulate matter and increases in morbidity or mortality.⁴² Many of these studies were based on PM₁₀ or TSP, because of the lack of data on PM_{2.5} concentrations.

Two studies aroused particular interest on the part of scientists, industry, Congress, and the public. In one, researchers tracked more than 550,000 participants from 1982-1989 in 154 U.S. cities.⁴³ This study is known as the American Cancer Society (ACS) Study.⁴⁴ In the other, researchers tracked just over 8,100 adults for 14-16 years in six U.S. cities beginning in the 1970s.⁴⁵ This study is known as the Six Cities Study.⁴⁶ Because EPA relied particularly (although not solely) on these studies in supporting its view that long-term exposure to fine particulate matter is associated

³⁶ 61 *Federal Register* 65642, December 13, 1996.

³⁷ 61 *Federal Register* 65642, December 13, 1996.

³⁸ 61 *Federal Register* 65643, December 13, 1996,

³⁹ EPA, *Criteria Document*, April 1996, Tables 13-3, 4, 5.

⁴⁰ 61 *Federal Register* 65643, December 13, 1996.

⁴¹ 61 *Federal Register* 65644, December 13, 1996.

⁴² 61 *Federal Register* 65646, December 13, 1996.

⁴³ Health Effects Institute, "Statement: Synopsis of the Particle Epidemiology Reanalysis Project." *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality*, July 2000 (includes Nov. 1, 2001 errata sheet), p. i. Available at [<http://www.healtheffects.org/Pubs/Rean-ExecSumm.pdf>], viewed November 21, 2004.

⁴⁴ Pope, C. Arden, III, et al. "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults." *American Journal of Respiratory and Critical Care Medicine* 151 (1995): 669-674.

⁴⁵ HEI July 2000, "Statement." p. i.

⁴⁶ Dockery, Douglas W. et al. "An Association Between Air Pollution and Mortality in Six U.S. Cities." *New England Journal of Medicine* 329 (1993): 1753-1759.

with mortality, many people wished to see the underlying data. The researchers who did the studies were concerned that releasing the data would violate the privacy of the studies' subjects. To solve this dilemma, the researchers agreed to release their data to the Health Effects Institute for re-analysis. The Health Effects Institute (HEI) was begun in 1980 and is funded jointly by industry and EPA to supply "high-quality, impartial, and relevant science on the health effects of pollutants from motor vehicles and from other sources in the environment."⁴⁷

HEI created a nine-member Expert Panel to provide oversight for the project and to select researchers to complete the re-analysis. This re-analysis team consisted of 30 epidemiologists and biostatisticians. After the re-analysis team completed its work, the research was peer-reviewed by a separate independent team of eight experts. HEI completed its re-analysis of the two studies in 2000.

The re-analysis was divided into two sections. First, the researchers attempted to replicate the results of the original studies. Then, researchers used different models and variables to determine the sensitivity of the results — that is, whether results would change when subjected to different approaches. In the first part of the project, researchers were able to replicate the results of the two studies using the original data and the same methods. In the second part, a number of sensitivity analyses were conducted. On the whole, these analyses did not materially change the results of the studies, although they did indicate the need for further research on particulate matter. HEI's conclusion was:

Overall, the Reanalysis assured the quality of the original data, replicated the original results, and tested those results against alternative risk models and analytic approaches without substantively altering the original finding of an association between indicators of particulate matter air pollution and mortality.⁴⁸

Particulate Matter Scientific Knowledge Since 1997

Increased Particulate Matter Research Funding. Congressional recognition of the need for more research on health effects of particulate matter, and the need to expedite research, led to an increased amount of funding directed toward such study. The FY1998 appropriations for EPA (P.L. 105-65) included language directing the National Academy of Sciences (NAS) to develop a research plan for particulate matter that EPA was to follow. Additional money for such research was appropriated above and beyond EPA's general budget. This action by Congress, based on consultation with EPA, NAS, and numerous scientific and research stakeholder groups, was one result of the controversy regarding the 1997 PM NAAQS. In particular, the Conference Report (H.Rept. 105-297) supporting the FY1998 appropriations noted that any research conducted with this funding would be available to the public, thus avoiding the controversy stemming from the ACS and Six Cities studies.

⁴⁷ Health Effects Institute. "What is the Health Effects Institute?" Available at [<http://www.healtheffects.org/about.htm>], viewed November 19, 2004.

⁴⁸ HEI, "Statement," July 2000, pp. i-ii.

The FY1998 appropriation more than doubled the funding provided to EPA for particulate matter research.⁴⁹ Congress increased funding in subsequent years, nearly tripling the funding in FY2001 compared to FY1997. Congress provided \$65.5 million for particulate matter research in FY2002, \$64.4 million in FY2003, and \$58.6 million in FY2004. The funding has supported numerous EPA intramural and extramural particulate matter research projects, and the establishment of five academically based particulate matter research centers around the country. The conference report (H.Rept. 108-892) for the FY2005 Consolidated Appropriations Act (P.L. 108-447) includes \$61.0 million for particulate matter research for FY2005.

National Academy of Science (NAS) Particulate Matter Research Priorities. NAS established the Committee on Research Priorities for Airborne Particulate Matter to fulfill the Congressional request. The committee has released four reports⁵⁰ pursuant to the legislation. The first report identified 10 priorities for particulate matter research. A description of how the committee is monitoring particulate matter research and revisions to the priorities were included in the second report. The priorities, as revised, are listed in **Table 2** presented on the next page. The third report provided a review of EPA's progress in particulate matter research from 1998 to mid-2000. The committee's fourth report, published March 24, 2004, is a final review of progress and includes recommendations for future directions in particulate matter research.

In the third report, the committee indicated that EPA had made some progress in targeting research for the priorities in the period 1998 to mid-2000, but found that other areas of particulate matter research were not proceeding as well. In the report, the committee designated research under six of the priorities (2, 3, 4, 6, 7, and 8) as either not proceeding as planned, not targeted toward the committee's priorities, or not yet adequate. The committee's report noted that research for priorities 1, 5, 9, and 10 was proceeding satisfactorily. An April 2002 HEI paper came to a similar conclusion. HEI indicated that current research is providing important information under research priorities 5, 9, and 10. According to HEI, particulate matter research has begun to determine what aspects of particles cause health effects, suggest what biological mechanisms may be responsible for particulate matter's reported health impacts, and identify which groups are most susceptible.⁵¹

⁴⁹ National Academy of Sciences, National Research Council, Committee on Research Priorities for Airborne Particulate Matter, *Research Priorities for Airborne Particulate Matter: III. Early Research Progress*. (Washington, D.C.: National Academy Press, 2000), p. 2 (hereafter Research Priorities III).

⁵⁰ The four reports are available from the National Academy of Sciences, National Research Council, Committee on Research Priorities for Airborne Particulate Matter, Washington, D.C., National Academy Press: *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio* (Report 1, 1998); *Research Priorities for Airborne Particulate Matter: II. Evaluating Research Progress and Updating the Portfolio* (Report 2, 1999); *Research Priorities for Airborne Particulate Matter: III. Early Research Progress* (Report 3, 2000); *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress* (Report 4, 2004). See [<http://www.nap.edu>].

⁵¹ Health Effects Institute, "Understanding the Health Effects of Components of the (continued...)"

Table 2. Research Priorities for Particulate Matter Identified by the National Academy of Sciences

Priority		Example Research Question
1	Outdoor Measures Versus Actual Human Exposure	How is the concentration of PM measured outdoors related to personal PM exposure?
2	Exposures of Susceptible Subpopulations	What components of PM most affect the health of particularly vulnerable people?
3	Characterization of Emissions Sources	What are the characteristics of PM emitted by primary sources?
4	Air-Quality Model Development and Testing	How are source emissions and ambient PM concentrations related?
5	Assessment of Hazardous PM Components	What aspects of PM negatively affect health?
6	Dosimetry	In vulnerable populations, where does PM deposit in the respiratory tract and where does it ultimately end up?
7	Combined Effects of PM and Other Pollutants	How can the effects of PM and the effects of other pollutants be separated?
8	Susceptible Subpopulations	Who is particularly vulnerable to PM?
9	Mechanisms of Injury	How does PM cause harm?
10	Analysis and Measurement	How do models and measurement errors affect risk estimates?

Source: Table prepared by Congressional Research Service, based on pages 39-93 of NAS report. National Academy of Sciences, National Research Council, Committee on Research Priorities for Airborne Particulate Matter, *Research Priorities for Airborne Particulate Matter: II. Evaluating Research Progress and Updating the Portfolio* (Washington, D.C.: National Academy Press, 1999).

In its fourth and final report released in March 2004, the NAS Committee on Research Priorities for Airborne Particulate Matter described the overall progress on several of the priority topics as “encouraging” and demonstrating that targeted research can resolve some key uncertainties. However, the committee determined that much remained to be done from the original research agenda.

The committee emphasized the characterization of emission sources (topic 3), air quality model development and testing (topic 4), and assessment of particulate matter hazardous components (topic 5). The need to advance the assessment of particulate matter hazardous components was identified as a central component for advancing several of the topic research areas, including developing targeted exposure studies under topic 2, refining emission inventories and models under topics 3 and

⁵¹ (...continued)

Particulate Matter Mix: Progress and Next Steps,” *HEI Perspectives: Insights from HEI’s Research Programs*, April 2002. Available at [<http://www.healtheffects.org/Pubs/Perspectives-2.pdf>].

4, advancing research on biological mechanisms under topic 9, and identifying susceptible subpopulations under topic 8. The committee identified the need for further methodological research as evidenced by recent findings on the sensitivity of time-series results to modeling approaches⁵² (see discussion in the next section of this report). The final NAS report contained extensive discussion of progress (or lack of progress) and recommendations for continuing under each topic area.

Research results under these topics reflect an expansion of the scope of health concerns and the emergence of new challenges since the committee's initial report in 1998. The report highlighted seven challenges for the coming years that are central to continuing the particulate matter research agenda:

- completing the particulate matter emission inventory and improving air quality models necessary for NAAQS implementation;
- developing a systematic program for accessing toxicity of particulate matter mixture components;
- enhancing air quality monitoring for research to serve multiple purposes;
- investigating the health effects of long-term exposure to air pollutants;
- improving toxicological approaches;
- expanding beyond a particulate matter research program to a multi-pollutant program;
- integrating research and collaboration across disciplines.

The conclusions in the committee's fourth report parallel EPA's own assessment of the particulate matter research program as presented in the agency's report released in September 2004. *Particulate Matter Research Program: Five Years of Progress*⁵³ highlights the research funded under the program, provides an update of what has been learned and summarizes future research challenges and recommendations. In the report, EPA contends that the research to date reconfirms links between exposure and serious health problems, has provided new evidence regarding cardiovascular effects, and where and how exposure occurs indoors and outdoors, and has resulted in the development of more sophisticated air measuring and modeling tools. However, despite these achievements, the agency emphasized that many uncertainties remain, and research must be expanded and redirected to address these gaps.

HEI-Sponsored National Morbidity Mortality and Air Pollution Studies. In 1994, the Health Effects Institute (HEI) initiated a research program to investigate the complex set of issues associated with human health effects of exposure to particulate matter. HEI has funded more than 40 studies and re-analyses

⁵² Subsequent to the release of the committee's third report, problems were identified with the application of a model and statistical package widely used in time-series analysis. The recognition of these problems required re-analysis of several research studies that were the basis for characterizing short-term risks associated with air pollutants.

⁵³ U.S. Environmental Protection Agency, Office of Research and Development, EPA 600/R-04/058, July 2004, at [<http://www.epa.gov/pmresearch>].

during the last 10 years, as well as several “special” reports on particulate matter research. As presented earlier in this report, HEI was responsible for the re-analyses of the ACS and Six Cities studies. Also, as part of their collaboration on particulate matter, EPA and HEI maintain a website where researchers can post current particulate matter research projects.⁵⁴ These projects are submitted to HEI and are reviewed by HEI staff before being posted on the website. The site includes more than 500 particulate matter projects.

A major area of focus for the HEI-sponsored particulate matter research has been uncertainties regarding the associated impacts of particulate matter on daily mortality, including the effects of other pollutants. In 1996 HEI provided funding initiating the National Morbidity, Mortality and Air Pollution Study (NMMAPS) conducted by researchers at Johns Hopkins University,⁵⁵ which to date has resulted in a series of three primary reports and several re-analyses. These analyses concluded that “PM₁₀ concentrations were positively associated with mortality and morbidity outcomes on average across locations.”

The initial report released in May 2000, NMMAPS I, was a compilation of methodological approaches for three topical priorities: measurement error in air pollution exposure, mortality displacement, and methods for combining evidence in multiple locations.⁵⁶ Results of the study, which included analyses of the 20 and 90 largest U.S. cities and hospital admissions of the elderly in 14 cities, were the basis of the second report — NMMAPS II.⁵⁷ This report was of particular interest because of its results, as well as the subsequent discovery by the authors of errors in a statistical software program used to analyze the data that lead to bias in the results (more discussion follows).

A third HEI-sponsored NMMAPS report (NMMAPS III),⁵⁸ published in May 2004, is a study of time-series data (1987-1994) of PM₁₀ effects on mortality for the 20 largest U.S. cities. The study examined the question of whether there is a threshold below which there does not appear to be an association between particulate

⁵⁴ The address is [<http://www.pmra.org>].

⁵⁵ Departments of Epidemiology and Biostatistics, Johns Hopkins School of Public Health, Baltimore MD, and Department of Environmental Health, Harvard School of Public Health. For copies of relevant publications and information regarding ongoing research visit [<http://www.biostat.jhsph.edu/biostat/research/update.main.htm>].

⁵⁶ Jonathan M. Samet, et al. *The National Morbidity, Mortality and Air Pollution Study Part I: Methods and Methodologic Issues (NMMAPS I)*, Final Version, Cambridge, MA, Health Effects Institute, no. 94, part I, October 2000. Available at [<http://www.healtheffects.org/Pubs/Samet.pdf>].

⁵⁷ Jonathan M. Samet, et al. *The National Morbidity, Mortality and Air Pollution Study Part II: Morbidity and Mortality from Air Pollution in the United States (NMMAPS II)*, Cambridge, MA: Health Effects Institute, no. 94, part II, 2000. Available at [<http://www.healtheffects.org/Pubs/Samet2.pdf>].

⁵⁸ Michael J. Daniels, et al. *The National Morbidity, Mortality and Air Pollution Study Part III: PM10 Concentrations-Response Curves and Thresholds for the 20 Largest U.S. Cities*, Cambridge, MA: Health Effects Institute, no. 94, part III, 2004. Available at [<http://www.healtheffects.org/Pubs/Daniels94-3.pdf>].

matter levels and mortality. A critique of the approach and results of the study by a Special Panel of the HEI Review Committee concluded that the development and application of complex statistical methods to describe concentration-response relationships has advanced the understanding of air pollutant health effects, and the results of the study have important implications for setting air quality standards.⁵⁹ However, because of several limitations presented in their review, the panel was apprehensive about the study's conclusions, and cautions drawing conclusions from the apparent absence of a threshold in the concentration-response relationship.

The original NMMAPS II report released in 2000 had found a 0.41% increase in daily mortality for every additional 10 $\mu\text{g}/\text{m}^3$ of PM_{10} for the 90 largest U.S. cities over an eight-year period. However, in May 2002, the researchers announced they had discovered errors in a statistical software program used to analyze the data and determined that the errors overstated this percentage. In a re-analysis, completed in 2002, researchers found a 0.27% increase.⁶⁰ Despite the error, the researchers stated that the conclusions of their report remain unchanged, namely:

Overall, this study provides strong evidence of association between PM_{10} levels and exacerbation of chronic heart and lung disease sufficiently severe to warrant hospitalization. The association cannot be explained by confounding [the presence of other pollutants] that is addressed in both stages of the analysis, although there is always the possibility of some residual confounding. Confounding by weather was considered above and can be set aside.⁶¹

The error was associated with the application of a general additive model (GAM) in the S-Plus statistical software. GAMs, effective for conducting nonlinear regression analysis of one or more variables (e.g., air pollution, weather, time), had been widely used in contemporary time-series research of health effects on air pollution and other similar applications since about 1990. The researchers found that their application of GAM in conjunction with the default convergence criteria in the software could result in upward or downward bias of estimated relative risk, potentially skewing the final results.⁶² The researchers conducted a re-analysis of the NMMAPS substituting alternative approaches in place of the model that created the error. In the re-analysis the researchers concluded that:

While the quantitative estimates changed with the tighter convergence criteria in the *gam* function or switching to GLM (approaches used in the re-analysis), the major scientific findings of the NMMAPS did not. Strong evidence remains of

⁵⁹ *NMMAPS III*, May 2004, p. 23-29.

⁶⁰ Francesca Dominici, et al., *A Special Report to the Health Effects Institute on the Revised Analyses of the NMMAPS II Data*, 2003, Health Effects Institute, Cambridge, MA. See also Joel Schwartz, et al., *A Special Report to the Health Effects Institute on the Revised Analyses of the NMMAPS II Data: Morbidity and Mortality Among Elderly Residents of Cities with Daily Measurements*, 2003, Health Effects Institute, Cambridge, MA.

⁶¹ *NMMAPS II*, 2000, p. 44.

⁶² Francesca Dominici, et al., *On the Use of Generalized Additive Models in Time Series Studies of Air Pollution and Health: Commentary*, *American Journal of Epidemiology* 2002, 156, pp. 193-203. Available at [<http://aje.oupjournals.org>].

an association between acute exposure to particulate air pollution (PM₁₀) and daily mortality one day later (lag 1). This association was strongest for respiratory and cardiovascular causes of death, as anticipated based on concepts of susceptibility.⁶³

The re-analyses of the NMMAPS were part of a larger effort for re-analyses of more than 40 selected time-series studies at the request of the EPA and the CASAC. HEI compiled its review of these re-analyses in a special report entitled *Revised Analyses of Time-Series Studies of Air Pollution and Health*, released in May 2003.⁶⁴

Re-analyses of Selected Time-Series Studies. The discovery of the problems⁶⁵ associated with certain applications of GAMs occurred as EPA was proceeding with its review of the inventory of scientific information for reassessment of the PM NAAQS. This model had been the basis for numerous particulate matter times-series studies conducted since 1990, many of which were the basis of EPA's review, and their results were potentially affected. The reported errors associated with the GAM had no effect on the results of the Harvard Six Cities Study and the American Cancer Society study, both of which were re-analyzed in depth and confirmed in 2000.

During the summer of 2002, EPA and the CASAC conducted an extensive evaluation of the studies included in the review. Roughly 40 studies were identified for re-analysis, including the NMMAPS. EPA requested that the researchers of the potentially affected studies conduct re-analyses to ensure the validity of their results, providing necessary guidance. The agency relied on the HEI to review the re-analyses and compile its evaluation of changes in the original results. HEI was not specifically tasked with evaluating the original designs and methods of the studies.

The HEI reported that overall, although the effects varied substantially across studies, the re-analyses resulted in estimates of effect lower than the original analyses. However, there continues to be an association of particulate matter with mortality/morbidity, particularly with respect to cardiovascular and respiratory diseases. The HEI review also commented that the revisions "renewed the interest in important questions and uncertainties that should inform future time-series analysis of air pollution and health."⁶⁶

Status of EPA's Review of the 1997 PM NAAQS

EPA's review of the 1997 PM NAAQS, which began not long after the current standards were promulgated,⁶⁷ is ongoing. As discussed previously in this report, the

⁶³ Francesca Dominici et al. 2003, p. 19.

⁶⁴ Health Effects Institute website, at [<http://www.healtheffects.org/Pubs/TimeSeries.pdf>].

⁶⁵ In addition to the concerns raised by the NMMAPS researchers, Health Canada found that the use of GAMs under certain conditions caused underestimates of standard errors.

⁶⁶ HEI, *Special Report*, May 2003, p. v.

⁶⁷ For details of EPA's original plans for reviewing the PM NAAQS, see 62 *Federal* (continued...)

CAA requires the criteria document for each criteria pollutant to be reviewed and, if appropriate, the NAAQS revised, every five years. As the implementation of the 1997 PM NAAQS has been delayed, so too has the review.

Schedule. The American Lung Association and several public interest groups filed an action in March 2003, in response to EPA's failure to meet the 2002 statutory deadline for review of the PM and ozone NAAQS. Through a consent decree⁶⁸ approved by the District Court of the District of Columbia on July 31, 2003, EPA and the parties to the lawsuit reached an agreement that included the establishment of deadlines for issuance of the particulate matter criteria document by July 30, 2004, a preliminary decision regarding revisions to the PM NAAQS by March 31, 2005, and final revised PM NAAQS (if deemed appropriate) by December 20, 2005.

On July 12, 2004, EPA filed an opposed motion for a further extension of the particulate matter criteria document until October 29, 2004, which was granted by the court. At the time of the motion, EPA expressed concern with its ability to meet the remaining deadlines, and the court, in its July 23, 2004 order, further directed the parties to consult to address the remaining consent decree deadlines. EPA shared a proposal for extending the remaining particulate matter deadlines with the plaintiffs on August 13, 2004, and it was later submitted to the court as part of a negotiation with the parties of the consent agreement.⁶⁹ Specifically, EPA proposed the following modifications to the PM NAAQS schedule:

- Extension from March 31, 2005, to December 31, 2005, to sign notice of proposed rulemaking setting forth its proposed decision concerning EPA's review of the PM NAAQS;
- Extension from December 20, 2005, to September 30, 2006, for EPA to sign a notice of final rulemaking setting forth EPA's final decision concerning review of the PM NAAQS.

As of December 2004, the plaintiffs, who have offered to continue consultations with EPA, were considering the agency's proposal.

2004 Particulate Matter Criteria Document. Following the federal court approval extending the deadline, EPA announced the availability of the updated criteria document, *Air Quality Criteria for Particulate Matter*, in the October 29, 2004, *Federal Register* (69 FR 63111). The 2004 criteria document is not intended to be a complete and detailed literature review, but rather a thorough evaluation of information relevant to PM NAAQS criteria development from pertinent literature that has become available between 1996 through April 2002. A few studies

⁶⁷ (...continued)

Register 55201, October 23, 1997.

⁶⁸ Consent agreement, July 2003, C.A. No. 03-778 (ESH), *American Lung Association, et al v. the U.S. Environmental Protection et al. (EPA)*, U.S. District Court for the District of Columbia.

⁶⁹ Joint Status Report, September 2004, C.A. No. 03-778 (ESH), *American Lung Association, et al v. the U.S. Environmental Protection et al. (EPA)*, U.S. District Court for the District of Columbia.

published through 2003 were determined to be critical to the assessment and included in the review. Although a primary focus of the review was on the latest available dosimetric and health effects data, other scientific data were also included to provide information on the nature, sources, size distribution, measurement, and concentrations of PM in the environment and contributions of ambient particulate matter to total human exposure.

The criteria document is the result of extensive public comment and rigorous review by experts from academia, various U.S. federal and state government units, non-governmental health and environmental organizations, and private industry. The document also reflects the review and deliberations of interim drafts, and the final approval and recommendations of the congressionally mandated CASAC. Drafts were revised in response to comments, and as necessary, to include relevant studies completed between drafts.

EPA issued its first draft of the criteria document in October 1999. A second draft was issued in March 2001, and included relevant studies through December 2000. Each of these two drafts was reviewed by CASAC and sent back with comments to the agency. EPA published a third draft of the criteria document in April 2002. CASAC reviewed this criteria document at its meeting in mid-July 2002. Although CASAC had originally indicated that closure on the criteria document was likely, assuming EPA made the modifications requested by CASAC in the second review,⁷⁰ CASAC did not close on the criteria document at the July 2002 meeting. EPA modified the criteria document to reflect changes to the outcomes of studies that were affected by the software problem found in the NMMAPS study.

Following the fourth external review in June 2003, the CASAC reached closure on Chapters 1 through 6 during its August 21-25, 2003, meeting, requiring only minor changes. The chapters on toxicology (Chapter 7), human health (Chapter 8), and integrative synthesis (Chapter 9) required extensive revision and restructuring. Additional CASAC and public reviews of the three revised chapters in December 2003 and June 2004 resulted in closure on Chapters 7 and 8. Chapter 9 continued to be reviewed and revised until CASAC completed its overall review⁷¹ after a September 20, 2004 teleconference.

The two-volume report contains extensive discussions of the findings and their relevance to establishing PM NAAQS in the context of the defined research priorities. The bullets below provide brief highlights of some of the conclusions excerpted from Chapter 9 of the 2004 criteria document, but without the associated details and caveats. Readers interested in the specific referenced findings should

⁷⁰ CASAC review, September 2001, *Review of the Air Quality Criteria Document for Particulate Matter: Second External Review Draft EPA (600/P-99/002bB): A CASAC Review*, letter to the Administrator, September 27, 2001, EPA-SAB-CASAC-LTR-01-001, p. 2. Available at [<http://www.epa.gov/sab/casac101001.pdf>].

⁷¹ CASAC final review, October 2004, *EPA's Fourth External Review Draft of Air Quality Criteria for Particulate Matter: A Peer Review by the Clean Air Scientific Advisory Committee Particulate Matter Review Panel*, U.S. EPA, EPA-SAB-CASAC-05-01. Available at [<http://www.epa.gov/sab/pdf/casac05001.pdf>].

refer to the corresponding sections of Chapter 9 (identified in parentheses) as well as relevant chapters in the document. The criteria document conclusions include the following:

- The 1996 recommendation that fine and coarse particles be considered as separate subclasses of particulate matter pollution is reinforced (Chap. 9, sec. 9.2.1);
- Epidemiological evidence continues to support likely causal associations between PM_{2.5} and PM₁₀ and morbidity and mortality from cardiovascular and respiratory diseases, but suggest no clear thresholds in particulate matter-mortality relationships (Chap. 9, sec. 9.2.2);
- New epidemiological re-analyses and extensions of previous studies show substantial evidence for increased lung cancer; toxicological evidence supports plausible association between particles (particularly fine particles) with physiological endpoints indicative of increased risk of heart disease, and supports plausible biological pathways for respiratory effects (Chap. 9, sec. 9.2.3);
- Recent studies support considering older adults and children as susceptible groups, given the overlap between age categories and pre-existence of cardiopulmonary diseases; evidence from toxicological studies suggests there are populations who are genetically predisposed to particulate matter-related effects (Chap. 9, sec. 9.2.4);
- Local visibility standards intended to reflect “adverse thresholds” associated with minimum visual range, and the criteria used to set these standards, may be relevant for consideration in assessing national secondary standards (Chap. 9, sec. 9.3.1);
- Considerable uncertainty remains with respect to the impact of the deposition of particulate matter on vegetation ecosystems; this issue requires additional research (Chap. 9, sec. 9.3.2);
- No significant advances have been made since the 1996 particulate matter review in reducing the uncertainties regarding the relationship of particulate matter to climate change processes (Chap. 9, sec. 9.3.3);
- Insufficient data with respect to pollutant concentration, particle size, and chemical composition continue to prohibit quantifying pollutant exposure levels that result in observable soiling and damage to man-made materials (Chap. 9, sec. 9.3.4).

EPA Particulate Matter Staff Paper. A draft staff paper issued in 2001 by EPA’s Office of Air Quality Planning and Standards for this new round of review did not contain any policy recommendations. However, a subsequent draft staff paper released in August 2003⁷² indicated that “the latest scientific, health and technical

⁷² Office of Air Quality Planning and Standards (OAQPS), U.S. Environmental Protection Agency, *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information*, EPA OAQPS Staff Paper — (continued...)

information *does not* support relaxing” EPA’s current PM NAAQS, and recommends that the agency consider revising standards to provide additional health protection. This is a *draft* paper and does not reflect the technical staff’s official final recommendations.

The staff paper will not be finalized until, as in the past, EPA technical staff interpret the most relevant information in the current criteria document and, combined with other relevant information, recommend options to be considered regarding policy decisions affecting the adequacy of the current 1997 PM NAAQS. The paper will not be used as the basis for any policy decisions until it is reviewed by the CASAC, others in the scientific community, industry, public interest groups, and the general public. As discussed earlier in this report, following its review of the staff paper, the CASAC panel will recommend improvements and eventually, after further meetings that are open to the public and reviews, sign off only when the panel are convinced that the paper accurately reflects the status of the science.

The staff assessment, in conjunction with the CASAC closure letter, will be used by the EPA Administrator to determine whether or not changes to the PM NAAQS are necessary. The CAA specifies that the Administrator shall use his/her “judgment ..., based on [the] criteria [document] and allowing an adequate margin of safety” to determine the NAAQS “requisite to protect the public health” (CAA, §109(b)(1)). Based on the recent EPA deadline proposal submitted for consideration by the court described earlier in this report, proposed modifications to the standards are not expected until December 2005, followed by a final rule in December 2006. As EPA proceeds with the review of the particulate matter criteria and standards, the agency is continuing implementation of the PM NAAQS promulgated in 1997.

Opposing Views, Potential Challenges and Litigation. As discussed earlier, the decisions by the Administrator of the EPA in July 1997 to revise ambient air quality standards (NAAQS) for ozone and particulate matter refocused attention on the criteria and the process by which these decisions are made. The new standards were the subject of numerous oversight hearings as well as litigation, which culminated in a Supreme Court ruling February 27, 2001.

Stakeholders continue to challenge the adequacy of the scientific data supporting the PM NAAQS. According to the EPA Docket,⁷³ numerous comments have been submitted throughout the current criteria document review process. Despite the agency’s attempts to be responsive to the concerns raised, varying interpretations of the data and their conclusions, and disagreements regarding which studies to include or not include, are likely to continue.

⁷² (...continued)

First Draft (EPA-452/D-03-001), August 2003. Obtained from EPA website at [http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html] on November 16, 2004.

⁷³ EPA Docket #OAR-2001-0017, available on EPA’s E-Docket website at [<http://docket.epa.gov/edkpub/index.jsp>], viewed November 22, 2004.

EPA's NAAQS rulemaking is subject to several statutory procedural requirements, compliance with which is subject to judicial review.⁷⁴ Given the history of the previous review and development of PM NAAQS, it is likely that litigation or other challenges will occur and potentially further delay the process.

Also, the agency's criteria document and subsequent staff paper could be challenged under the Data Quality Act (DQA; also referred to as the Information Quality Act), enacted in December 2000.⁷⁵ Intended to ensure quality, objectivity, utility, and integrity of information, the DQA required the Office of Management and Budget (OMB) to issue policy and procedural guidance to federal agencies. The act required each covered agency to issue its own information quality guidelines within one year of the issuance of the OMB guidelines. Following review and comment on earlier proposals, OMB published its guidelines on February 22, 2002 (67 *Federal Register* 8452)⁷⁶ and agency guidelines were subsequently developed and reviewed by OMB.⁷⁷

Those who have submitted public comment in response to a federal agency action and who are dissatisfied with how their correction requests were handled through the Administrative Procedures Act process could appeal that agency's decision through the DQA administrative appeal process. For additional background regarding the DQA, see CRS Report RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation*.

EPA will likely encounter more extensive challenges following its determinations regarding revisions to the 1997 PM NAAQS. The first suits challenging the ozone and 1997 PM NAAQS were filed in the D.C. Circuit Court of Appeals on July 18, 1997, the day the final rules appeared in the *Federal Register*. During 1997 a total of 38 suits were filed for judicial review of various aspects of the ozone and PM NAAQS. These suits were consolidated in the *American Trucking Associations v. U.S. E.P.A.*, argued December 17, 1998, and decided May 14, 1999 (175 F.3d 1027 (D.C. Cir. 1999)). Many of the stakeholders who were party to those lawsuits are expected to continue to challenge the justification of the current standards as well as modifications as a result of the current review.

The 1997 standards have been attacked both as overly stringent and as inadequately protective of health; as ignoring costs and as giving costs too much deference; as going beyond what is scientifically conclusive; and as failing to be

⁷⁴ The basic framework is spelled out in the CAA, §307(d) (42 U.S.C. §7607(d)) and details the requirements for public notice and participation in the process.

⁷⁵ Enacted in December 2000 as Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554) (44 U.S.C. 3504(d)(1) and 3516).

⁷⁶ For a copy of the OMB guidelines, see [<http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf>].

⁷⁷ Agencies' guidelines are published on OMB's website, although it cautioned the public that the list is not complete and will be updated as more guidelines are posted online. See [http://www.whitehouse.gov/omb/inforeg/agency_info_quality_links.html].

sufficiently precautionary.⁷⁸ EPA's general interpretation of the criteria supporting NAAQS has been the subject of various challenges. Some have argued, and continue to argue, that the science does not enable the agency to establish a clear threshold, and if there is no "threshold," then there cannot be a "margin of safety" as required by the CAA. As a result, the whole NAAQS process of necessity becomes a risk management decision — that is, one in which the EPA Administrator balances risks with costs to decide where to set the standard. Others argue that the lack of a threshold justifies the tightest possible standards.

Another, continuing debate comes from the view that only in adding a margin of safety does the Administrator layer a policy judgment onto an objective — scientifically determined NAAQS. Some argue that this judgmental aspect means that the margin of safety phrase implicitly endorses the consideration of costs in setting NAAQS; as discussed later, the lead industry sued EPA over lead standards on the basis that the margin of safety required EPA to take costs into account in setting NAAQS, but the court ruled that the statute and its legislative history are against that interpretation (*Lead Industries Association v. Environmental Protection Agency*, 647 F.2d 1130 (D.C. Cir. 1980)).

These issues were the subject of numerous oversight hearings as well as litigation, which culminated in the Supreme Court ruling of February 27, 2001 (discussed earlier in this report). The court upheld those NAAQS setting procedures at question, in particular definitively rejecting the consideration of costs in setting NAAQS.

Implementation of the 1997 PM NAAQS

PM_{2.5} Monitoring Network. Revising the PM NAAQS in 1997, which added standards for PM_{2.5}, necessitated establishing a monitoring network to measure the fine particles. At the time the new NAAQS were being finalized, EPA also developed methods for monitoring fine particles. Using funding specifically authorized for this purpose in EPA appropriations FY1998-FY2000,⁷⁹ the agency worked closely with states and tribes to initiate the deployment of a portion of the network of 1,200 monitors in January of 1999.

PM_{2.5} attainment or nonattainment designations are to be made primarily on the basis of three-year federally referenced PM_{2.5} monitoring data.⁸⁰ The majority of the monitors were not in place until January of 2000; therefore, the necessary three years of data became available at the end of 2002. In response to the need for additional time to establish effective PM_{2.5} monitoring, and other delays, Congress mandated

⁷⁸ See CRS Report 97-8, *Air Quality: EPA's New Ozone and Particulate Matter Standards*.

⁷⁹ Appropriations for monitoring averaged roughly \$50 million per year, P.L. 105-65, P.L. 105-226, P.L. 106-74.

⁸⁰ A federally referenced monitor is one that has been accepted for use by EPA for comparison of the NAAQS by meeting the design specifications, and certain precision and bias (performance) specifications (40 *Code of Federal Regulations* Part 58).

that EPA designate nonattainment areas for the PM_{2.5} standard by the end of 2005 (Title VI of the 1998 Transportation Equity Act for the 21st Century, P.L.105-178).

Operation of the network of monitors was phased in from 1999 through 2000, making three-year monitoring data available at different points depending on area location. Rather than a staggered designation schedule that would likely result in hampering cross-coordination of implementation plans, the EPA proposed a single date for state/tribal recommendations and final EPA designations. In the agency guidance, states/tribes were expected to rely on data collected during 2000-2002 for their area designation recommendations. EPA considered the 2001-2003 data to make the final designations.

PM_{2.5} Attainment/Nonattainment Geographical Designation.⁸¹ An area designated as nonattainment is defined as any area that does not meet, or that contributes to ambient air quality in a nearby area that does not meet, an air quality standard. Nonattainment designation begins a process in which states (and tribes) must develop and adopt emission control programs sufficient to bring air quality into compliance by an EPA defined deadline.

The CAA (Section 107(d)(1)(A); 42 U.S.C. 7407) establishes a cooperative federal-state/tribe⁸² process for designating nonattainment areas and setting their boundaries. However, it provides the EPA Administrator discretion in determining the final boundaries. Based on provisions of the CAA and non-binding EPA guidance, 18 states and the District of Columbia recommended 145 counties as potential nonattainment areas for PM_{2.5} NAAQS at the end of February 2004.⁸³

By the end of June 2004, EPA completed its review of the state/tribe submissions and, using its authorized discretion, recommended modifications resulting in nonattainment designations for 244 counties in 21 states and the District of Columbia. As required by statute, the EPA notified each of the affected states regarding its specific modifications to allow sufficient opportunity to provide new information and demonstrate why a proposed modification was inappropriate. Some states responding to the EPA's proposal continued to support their original recommendations.

⁸¹ For a more detailed discussion of the implementing the 1997 PM NAAQS and the associated designation process and associated issues, see CRS Report RL32431, *Particulate Matter (PM_{2.5}): National Ambient Air Quality Standards (NAAQS) Implementation*.

⁸² Tribes are not required, but were encouraged, to submit PM area designation recommendations. The area designation requirements under the CAA (Section 107) are specific with respect to states, but not tribes. EPA plans to follow the same designation process for tribes per sections 110(o) and 301(d) of the CAA and pursuant to the 1988 Tribal Authority Rule, which specifies that tribes shall be treated as states in selected cases (40 *Code of Federal Regulations* Part 49). Tribes have participated in the PM_{2.5} designation recommendation process, recommending designations of attainment/unclassified (see [<http://www.epa.gov/pmdesignations>]).

⁸³ For PM_{2.5} geographical designation recommendations from individual states and tribes, see EPA's "PM_{2.5} Designations" website at [<http://www.epa.gov/pmdesignations>].

EPA's final nonattainment designations for all or part of 225 counties in 20 states, and the District of Columbia, published in the January 5, 2005, *Federal Register*, reflect minor modifications to its June 2004 proposal. The modifications are primarily the result of removing 19 counties from the list of nonattainment areas, and redefining other counties by designating only specified geographical locations ("partial") within the county as nonattainment.

The final PM_{2.5} designation rule allows states to submit no later than February 22, 2005, certified, quality-assured 2004 monitoring data that suggests a change in designation is appropriate for consideration (70 *Federal Register* 948). A nonattainment designation could be withdrawn if the EPA agrees that the additional data warrants such a change.

Other Activities Impacting PM NAAQS Implementation

Current CAA Regulation. EPA has concluded that in many cases, PM_{2.5} attainment will be reached as the result of implementing strategies developed under the 1999 visibility protection regulations ("Regional Haze Rule")⁸⁴; voluntary diesel engine retrofit programs; new federal standards on cars, light trucks, and heavy duty diesel engines that are scheduled to be implemented between 2004 and 2010; and the 1998 regional strategy to reduce nitrogen oxides from eastern states referred to as the "NOx SIP Call."⁸⁵ Although it was primarily designed to meet the ozone NAAQS, EPA predicts the NOx SIP call will also provide some benefits in terms of reduced levels of nitrate fine particles.

According to a December 2004, EPA report, *The Particle Pollution Report: Current Understanding of Air Quality and Emissions through 2003*, monitored concentrations of PM_{2.5} have decreased 10 percent, and PM₁₀ have decreased 7 percent since 1999, primarily in areas with the highest concentrations.⁸⁶ EPA attributes a large portion of these decreases to the Acid Rain Program.

On April 15, 2004, EPA designated areas in 32 states and the District of Columbia (474 counties) as "nonattainment areas" for a new ozone air quality standard.⁸⁷ Many of the areas designated nonattainment for the new ozone standards are likely to be the same as those designated for PM NAAQS, and the approaches to control ozone included in state implementation plans will likely control particulate

⁸⁴ 64 *Federal Register* 35714, July 1, 1999. EPA recently published a proposal revising the regional haze rule, intended to provide guidelines for state and tribal air quality agencies to use in determining how to set air pollution limits (69 *Federal Register* 25184, May 5, 2004). See CRS Report RL32483, *Visibility, Regional Haze, and the Clean Air Act: Status of Implementation*.

⁸⁵ 64 *Federal Register* 35714, October 27, 1998. For background see CRS Report RS20553, *Air Quality and Electricity: Initiatives to Increase Pollution Controls*.

⁸⁶ U.S. Environmental Protection Agency, EPA 454-R-04-002, December 2004. Revised report posted on EPA's website [<http://www.epa.gov/airtrends/pm.html>], December 23, 2004.

⁸⁷ See CRS Report RL32345, *Implementation of EPA's 8-Hour Ozone Standard*.

matter, including PM_{2.5} indirectly. The agency's non-binding guidance for PM_{2.5} area designations recommended that states/tribes consider using the same boundaries for nonattainment for both the PM_{2.5} and 8-hour ozone standards, to facilitate consistency in future implementation plans.

Proposed Regulations and Legislation. Proposed legislation and EPA regulations for controlling coal-fired electric power plants' emissions, such as "Clear Skies"/multi-pollutant legislation and the proposed "Clean Air Interstate Rule" (CAIR, also referred to as the Interstate Air Quality Rule" (IAQ)) to be implemented between 2004 and 2015,⁸⁸ could also contribute national and regional measures for attaining PM_{2.5} standards. The EPA predicts that, of an estimated 120 eastern counties out of compliance with PM_{2.5} NAAQS in 2002, the Clean Air Interstate Rule will bring 28 more counties into compliance in addition to the 58 counties predicted to come into compliance under existing programs.⁸⁹ The extent of pollution reduction that is projected as a result of these proposals has been the subject of considerable debate among stakeholders, and some Members of Congress.

California Particulate Matter Standards. States are permitted to adopt more stringent ambient air quality standards than EPA's NAAQS. Since 1982, California has had more stringent particulate matter standards than the national standards. California's standards for PM₁₀ are 30 µg/m³ annual geometric average and 50 µg/m³ 24-hour average, as compared to EPA's 1997 PM₁₀ standards of 50 µg/m³ annual arithmetic mean and 150 µg/m³ 24-hour average.

In 1999, the California legislature passed a bill requiring examination of the standards for their adequacy in protecting health, particularly that of children. A December 2000 report by the California Air Resources Board (CARB) found that the PM standards were not adequate to protect human health. The 1999 California law mandated revision of these standards by December 31, 2002. California's process for revision is somewhat similar to EPA's NAAQS revision process in that a staff paper is produced and an Air Quality Advisory Committee reviews the report.

In May 2002, CARB staff published a paper suggesting revising the standards for PM₁₀ and establishing new standards for PM_{2.5}. The staff paper maintained the level and form of the 24-hour PM₁₀ standard but tightened the annual standard to 20 µg/m³ annual arithmetic average, not to be exceeded. The new standards for PM_{2.5} were recommended to be 12 µg/m³ annual arithmetic average, not to be exceeded, and 25 µg/m³ 24-hour average standard, not to be exceeded. The staff had not originally recommended a 24-hour standard for PM_{2.5}, but did so after the Air Quality Advisory Committee concluded that adequate information existed to set a standard.

In June 2002, CARB held a public hearing on the staff paper recommendations. Because of the software problem revealed in the NMMAPS study discussed above, CARB decided not to include the PM_{2.5} 24-hour standard on the agenda for the

⁸⁸ For a further discussion, see CRS Report RL31779, *Air Quality: Multi-Pollutant Legislation in the 108th Congress*, and CRS Report RL32273, *Air Quality: EPA's Proposed Interstate Air Quality Rule*.

⁸⁹ CRS Report RL32273, *Air Quality: EPA's Proposed Interstate Air Quality Rule*, p. 11.

meeting because some of the studies supporting the standard had used the faulty software. At the meeting, CARB unanimously approved the three other particulate matter standard recommendations. Following the required administrative law review, the standards became effective July 5, 2003. **Table 3** compares California's 1982 standards, California's 2002 standards, and EPA's 1997 PM NAAQS.

Table 3. California's State Particulate Matter Standards and the 1997 National Primary Particulate Matter Standards

	California's 1982 State Standard	California's 2002 State Standard	1997 National Primary Standard
Indicator	PM ₁₀	PM ₁₀ and PM _{2.5}	PM ₁₀ and PM _{2.5}
Form	24-hour average (not to be exceeded) Annual geometric mean (not to be exceeded)	24-hour average (not to be exceeded) Annual arithmetic mean (not to be exceeded)	24-hour average (concentration-based percentile) Annual arithmetic mean
24-hour NAAQS	50 µg/m ³	PM ₁₀ : 50 µg/m ³ PM _{2.5} : none	PM ₁₀ : 150 µg/m ³ (99 th percentile) PM _{2.5} : 65 µg/m ³ (98 th percentile)
Annual NAAQS	30 µg/m ³	PM ₁₀ : 20 µg/m ³ PM _{2.5} : 12 µg/m ³	PM ₁₀ : 50 µg/m ³ PM _{2.5} : 15 µg/m ³

Source: Prepared by the Congressional Research Service.

California is currently considering amendments to its designation criteria, and current area designations to account for the particulate standards adopted in June 2002. Legislation signed by the governor on October 8, 2003, required additional specific requirements for PM₁₀ and PM_{2.5} nonattainment areas. California Senate Bill 656 (SB 656)⁹⁰ requires the development and adoption of a list of the "most readily available, feasible, and cost-effective control measures to reduce PM₁₀, PM_{2.5}, and their precursor emissions," by January 1, 2005.

California's decision on particulate matter may have national ramifications, although no other states have set particulate matter standards different from the federal standards. How California's actions regarding particulate matter might impact EPA's decision upon conclusion of its current review is unclear.

International Particulate Matter Standards. Several countries have established relatively comparable air quality standards for a number of the same pollutants as the U.S., including particulate matter. A recent study⁹¹ compared various aspects of the U.S. air quality and water quality standards with those of other countries. According to the study, the U.S. standards for PM₁₀ are less stringent than

⁹⁰ For more information, see the California Air Resources Board website at [<http://www.arb.ca.gov/pm/pmmeasures/pmmeasures.htm>].

⁹¹ Timothy Benner, "Brief Survey of EPA Standard-Setting and Health Assessments," *Environmental Science and Technology*, vol. 38, no. 13, 2004. Published on the American Chemical Society website at [<http://pubs.acs.org/>].

64% of the countries identified. Canada is the only other country that currently has standards for PM_{2.5}; their 24-hour standard is more stringent (30 µg/m³) than the U.S. 24-hour standard (65 µg/m³). Several countries include standards for total suspended particulates (TSP), which U.S. EPA discontinued regulating in 1987 when the agency focused attention on PM₁₀.

For purposes of illustration, **Table 4** (below) presents comparisons of U.S. PM₁₀ and PM_{2.5} standards with standards in other selected countries as reported in the study. The comparisons of the various countries' particulate matter standards in this survey introduce interesting insights and raise empirical questions about why they differ. The significance of these differences requires a more complete understanding of the individual statutory authority, the data and interpretations of the data, and other factors each country used in establishing their standards, as well as their intended outcomes in terms of particulate matter emissions.

Table 4. PM₁₀ and PM_{2.5} Air Quality Standard Comparison of United States and Selected Countries

	US	EU	Brazil	China	France	Germany	India	Mex.	N.Z.	S.Africa	Spain	UK
PM₁₀ (µg/m³)												
24-hour	150	50	150	150	50	50	100	150	50	180	50	50
Annual	50	20 ^a	50	100	40	40	60	50	20	60	20 ^a	40

Source: Prepared by the Congressional Research Service based on "Brief Survey of EPA Standard-Setting and Health Assessment," by Timothy Benner, U.S. Environmental Protection Agency, Office of Research and development, Office of Science Policy. Published by the American Chemical Society May 28, 2004. As printed in *Environmental Science and Technology*, vol. 38, no. 13, 2004.

^a Final 2010.

Some of the differences are likely to be the result of different interpretation of the same data. In addition, the U.S. was among the first to establish standards for particulate matter; several other countries are only now considering comparable PM_{2.5} standards. The lag in establishing particulate matter standards by other countries may be part of the reason for the comparable stringency in the PM₁₀ standards. Other countries that established these standards later than the U.S. had the advantage of expanded information. As noted in the study, an important consideration with regard to this type of comparison is the implementation and adequacy of enforcement regulations for actually achieving improved air quality. According to the study, although it varies from country to country, EPA's implementation and enforcement appears to be more successful than most other countries.

The level at which other countries are setting their particulate matter standards might be indicative of an emerging international agreement regarding the scientific knowledge about particulate matter health effects. However, it is not clear if the comparison of the U.S. particulate matter standards to those of other countries will be a factor as EPA continues the simultaneous review and implementation of the current PM NAAQS.

Conclusions

Particulate matter standards have been a source of significant controversy. EPA's promulgation of standards for both coarse and fine particulate matter in 1997 prompted critics to charge EPA with over-regulation and spurred environmental groups to claim that EPA had not gone far enough. Not only was the science behind the PM NAAQS challenged, but EPA was also accused of unconstitutional behavior. However, EPA's decision to issue these standards was upheld, for the most part, and the science behind the standards was generally vindicated by an HEI review.

EPA is proceeding with its review of new information to determine whether further revision of the PM NAAQS is necessary. Congress's provision of significantly more funding for particulate matter research has resulted in an increased number of ongoing studies to determine particulate matter health effects. Recent scientific findings in the NMMAPS and other related research have prompted further concern about the health effects of particulate matter. However, a number of stakeholders still contend that the scientific does not adequately support the PM NAAQS.

As EPA evaluates the need to revise current PM NAAQS, stakeholder interest remains high. PM_{2.5} standards are expected to affect numerous areas, including some that have not previously been designated nonattainment for a NAAQS. This has raised concerns regarding the potential impacts, and triggered numerous questions regarding the specifics of the implementation process. EPA projects that federal measures, such as recent auto and truck emission standards and controls on power plants, will be sufficient to demonstrate attainment in a large portion of monitored nonattainment counties by 2015, and help alleviate the development and implementation of local measures. Some Members of Congress, and others, have questioned the agency's predictions regarding the relative magnitude of the emission reductions associated with existing and proposed air quality controls.

If EPA decides to tighten the PM NAAQS again based on the results of its review, more areas could be classified as nonattainment and need to implement new controls on particulate matter. This would require states and local governments to develop and implement new plans for addressing emissions in those areas that do not meet any new standards. A stricter standard may mean more costs for these transportation and large industries, including utilities, refineries, and the trucking industry, impacted by particulate matter controls. In terms of public health, a stricter standard may mean fewer health effects for the general population and particularly sensitive populations such as children, asthmatics, and the elderly. Because both the health and economic consequences of particulate matter standards are so potentially significant, the PM NAAQS are likely to remain a prominent issue of interest to many, including Members of Congress.

Actions following the release of the 8-hour ozone designations will likely affect certain decisions and the schedule regarding PM_{2.5}. In addition, California and several countries have established particulate matter standards that are more stringent than the current U.S. standards. Whether these actions can be considered indicative of what EPA will decide to do in its current review of the PM NAAQS is unclear.

The agency's previous review and establishment of PM NAAQS was the subject of litigation and challenges, including a Supreme Court decision in 2001. It would not be surprising if interested parties return to the courts or initiate challenges under the 2000 Data Quality Act in the months ahead, as the agency continues its review and implementation of the PM NAAQS. Thus, the final form of the current efforts to implement the PM_{2.5} standards, and EPA's response to the current review of PM NAAQS and the science information, may not be known for some time. It could be some time before the final form of the PM NAAQS resulting from the current EPA review is known. Likewise, the EPA's current PM_{2.5} implementation efforts could also potentially be delayed.