The 1987 Revision of the NAAQS for Particulate Matter and the 1993 Decision Not to Revise the NAAQS for Ozone: Two Case Studies in EPA's Use of Science

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Abstract

This paper discusses EPA's acquisition and use of science in two decisions regarding National Ambient Air Quality Standards: the 1987 Revision of the NAAQS for Particulate Matter and the 1993 Decision Not to Revise the NAAQS for Ozone. In the first case, more than ten years before EPA proposed to revise the NAAQS for particulates, narrowly-scoped results of academic experiments suggesting that the agency should focus its regulatory efforts on smaller diameter suspended particulates penetrated deep into the agency, far removed from decisionmakers in Washington. The particulates review was elaborate and protracted and was promoted and inhibited by multiple factors. Due to the lengthy review period, however, researchers involved in complex epidemiological studies were able to produce information which bore directly on regulator's questions prior to the final decision. Such is a rarity given the normal mismatch between the pace of regulatory decisionmaking and the time required to produce, analyze, and verify original scientific data. These studies observed an increase in respiratory ailments in children at particulate concentrations experienced in U.S. urban areas and suggested the lack of a discernible threshold in the relationship between particulate levels and mortality. Furthermore, as the decision was being finalized, the agency leadership was warned that forthcoming studies would probably suggest health concerns at even lower levels than the lowest end of the proposed range. In the case of ozone, political factors and a divided Clean Air Science Advisory Committee (CASAC) led to a 1992 proposal by EPA Administrator Reilly not to revise the NAAQS for ozone. Administrator Browner essentially inherited this decision during the transition period between the Bush and Clinton administrations, and although the role of science in the final decisionmaking was not substantive, the scientific review *process* was considered. The ozone case study illustrates that an elaborate and lengthy NAAQS review process is required to make science available for consideration by EPA decisionmakers and that *policy* disagreements within CASAC provide the Administrator with a justification to not revise the NAAQS on the basis of "scientific uncertainty." Both cases provide examples of non-agency scientists operating in multiple, overlapping roles inside and outside the regulatory decisionmaking process. The NAAQS case studies also underscore that the Clean Air Act is based on the false scientific premise that a threshold level exists below which health effects from ubiquitous air pollutants will not be observed. As a consequence of this mistaken legislative presumption, new scientific developments inevitably point toward ever more stringent ambient standards and preordain--in principle--the outcome of periodic reviews of the scientific basis of air quality regulation. In practice, EPA's response has been to delay the inevitable.

Abstract

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INTRODUCTION

The case studies included in this discussion paper are part of a project that Resources for the Future (RFF) is conducting under a cooperative agreement with the U.S. Environmental Protection Agency (EPA) and with general support from RFF. The case studies were originally vetted as RFF Discussion Paper 97-07 in 1996, and this revised version of the discussion paper reflects many useful comments and corrections supplied by reviewers.

The overall study is broadly concerned with the acquisition and use of scientific information by the Environmental Protection Agency in regulatory decisionmaking. The overall study focuses chiefly on national rulemaking (e.g., setting National Ambient Air Quality Standards and banning pesticides or toxic substances), as opposed to site-specific decisionmaking (e.g., Superfund remedy selection). For the purposes of this study, environmental "science" refers to information that can be used in assessing risks to human health, welfare, and the environment. (Therefore, economic and engineering information are not a chief focus of this study.) The project aims to help policymakers and others better understand the factors and processes that influence EPA's acquisition and use of science in national rulemaking so that they can better evaluate recommendations for improving environmental regulatory institutions, policies, and practices.

In all, eight case studies will be included as appendices to the full report:

- 1987 Revision of the National Ambient Air Quality Standard for Particulates (NAAQS)
- 1993 Decision Not to Revise the NAAQS for Ozone
- 1991 Lead/Copper Rule under the Safe Drinking Water Act (SDWA)
- 1995 Decision to Pursue Additional Research Prior to Revising the Arsenic Standard under SDWA
- 1983/4 Suspensions of Ethylene Dibromide under the Federal Insecticide, Fungicide, and Rodenticide Act
- 1989 Asbestos Ban & Phaseout Rule under the Toxic Substances Control Act
- Control of Dioxins (and other Organochlorines) from Pulp & Paper effluents under the Clean Water Act (as part of the combined air/water "cluster rule" proposed in 1993)
- Lead in Soil at Superfund Mining Sites

The case studies were selected in consultation with informal advisors to the project and are not intended as a random or representative sample of EPA regulatory decisions. None of the case studies could be fairly characterized as routine or pedestrian. As a group, the cases tend toward the "high-profile" end of the distribution of EPA decisions. Nevertheless, among the case studies, there is some variability in the political and economic stakes involved and in the level of development of the underlying science. The cases selected involve each of the "national" environmental regulatory statutes (Clean Air Act; Safe Drinking Water Act; Toxic Substances Control Act; Federal Insecticide,

Fungicide, and Rodenticide Act; and Clean Water Act), and two cases involve decisions to maintain the status quo (ozone and arsenic), as opposed to the remainder of the cases which involve decisions to change from the status quo.

Methodology

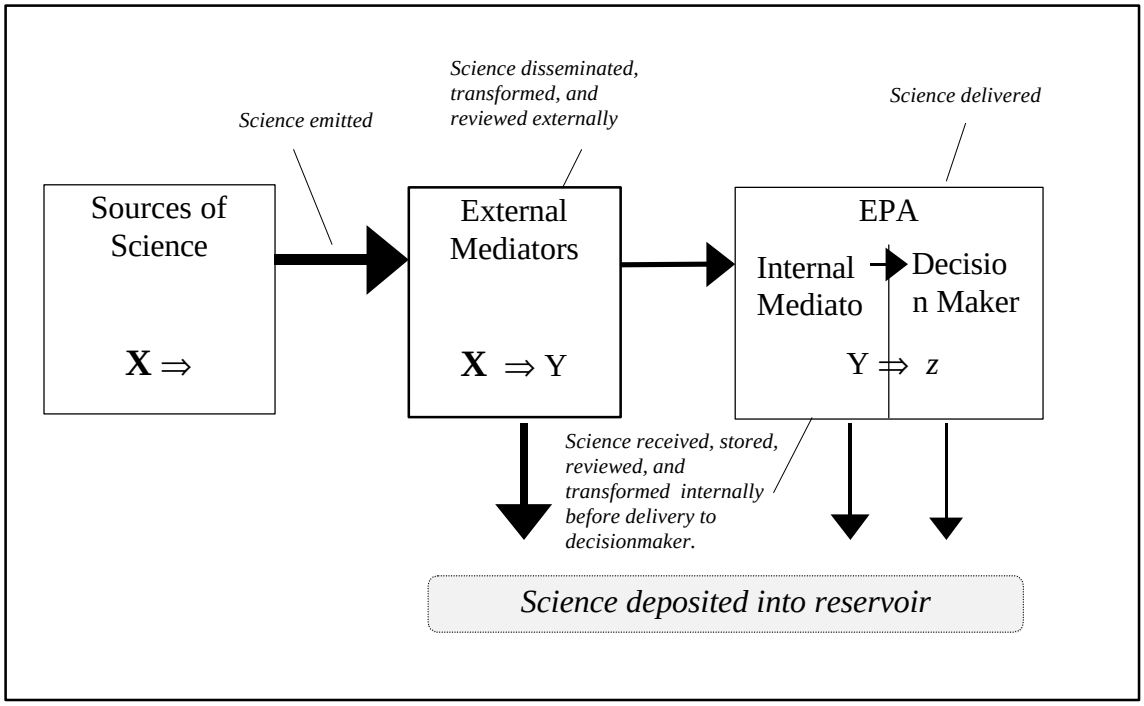
Development of the case studies was based on literature review and interviews with persons inside and outside EPA. The number of interviewees per case study varied roughly from a half dozen to a dozen. There was an effort to ensure balance in the group of respondents for any particular case study, but because of the relatively small number of respondents and the non-random nature of the selection process, *extreme* caution should be taken in interpreting the numerical response summaries that are reported. Interviews were conducted primarily using a structured questionnaire format, but in some cases, comments were sought from specific individuals regarding particular issues instead of the case as a whole. In addition to interviews specific to particular case studies, interviews were also conducted for the overall study to elicit the views of current and former policymakers, senior scientists, specialists in regulatory science issues, and others regarding EPA's acquisition and use of science. The case studies also incorporate many comments and insights from these interviewees.

In all instances, interviewees were given the option of speaking for attribution or off-the-record, and almost all respondents elected to speak off-the-record. A complete listing of the more than 100 interviewees for the overall study will be included as an appendix to the final report. The selection of interviewees considered that individuals from the bench scientist through the agency staff analyst to the politically appointed decisionmaker, as well as advocates from outside the agency, would provide informative perspectives. Among the wide range of interviewees were: 5 of 6 former EPA Administrators, 4 current or former Deputy Administrators, and 5 current or former Assistant Administrators; 4 current or former congressional staff; several current and former EPA Science Advisory Board members; various representatives of industry and environmental advocacy groups; environmental journalists; and academics from the diverse fields of biology, public health, economics, political science, psychology, and philosophy. But to better understand the processes occurring *within* the agency, interviewees were disproportionately selected from among current and former EPA officials.

A prominent feature of the case studies consists of an effort to map the origins, flow, and effect of scientific information relating to a particular decision. To accomplish this, the case studies make use of an extended analogy to fate and transport modeling. As used in risk assessment, this modeling procedure predicts the movement and transformation of pollutants from their point of origin to their ultimate destination. Thus, to extend the analogy, one can imagine universities and research institutes "emitting" scientific findings, which are disseminated and "transformed" by the media and consultants outside the agency. (An alternative pattern is when scientific findings are generated within EPA by agency scientists.) Science can enter EPA through multiple "exposure routes," which assimilate information differently; once inside the agency, information is

"metabolized" prior to its "delivery" to the "target organ" (the decision-maker). This fate and transport terminology is adopted because it is part of the vernacular of many of those providing the information and of many of the ultimate users of the study results. Figure A presents a simplified model of the fate and transport of science in environmental regulation for illustrative purposes.

Figure A. Fate and Transport of Science in Environmental Regulation



Making use of these conceptual models, we attempt to address questions specifically about the *scientific information* in each of the case studies, such as: what are the sources and their relative contributions? where are the points-of-entry? who are the gatekeepers? what is the internal transport mechanism? how is the information transformed as it flows through the agency? what does and doesn't get communicated to the decisionmaker? and where and how is the information ultimately applied?

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A. The 1987 Revision of the NAAQS for Particulate Matter

1. Background

In October 1948, a dense fog blanketed Donora, PA. Approximately 40% of the population of 10,000 suffered some ill symptoms. Twenty people, mostly adults with pre-existing cardiopulmonary conditions, died during or shortly after the fog. A series of similar winter episodes occurred in London between 1948 and 1962 (EPA 1982a). In retrospect, the cause of these public health episodes--air pollution trapped by thermal inversions--seems painfully obvious. However, several years passed before scientists excluded alternative potential causes and identified air pollution as the culprit. Beginning in 1963 and culminating in 1990, Congress enacted an escalating series of statutes to address air pollution on a national basis.

The 1963 Clean Air Act (CAA) directed the Department of Health, Education, and Welfare (HEW) to prepare Criteria Documents (CDs) (hence the term "criteria" air pollutants) summarizing scientific information on widespread air pollutants for use by state and local public health agencies. The 1967 Air Quality Act specified the role of CDs in the development of state air quality standards. A year later, the Surgeon General established a National Air Quality Criteria Advisory Committee to review and advise on CDs. In 1969, HEW produced the original CD for particulate matter (PM). On the basis of HEW's CD, and in response to the 1970 CAA Amendments, EPA promulgated the first National Ambient Air Quality Standards (NAAQS) for PM in April 1971 (36 *Fed. Reg.* 8186).[1]

The 1970 CAA also required that the NAAQS be based on air quality criteria that reflect the latest scientific information and that both the criteria and standards be periodically reviewed and, if appropriate, revised. In 1976, as a result of internal EPA review and recommendations of the EPA Science Advisory Board (SAB),[2] the agency decided to revisit all of the criteria air pollutants, with work scheduled to begin on a combined PM/sulfur oxides (SO_x) Criteria Document in 1979.[3] Dissatisfied with EPA's progress in re-evaluating the original NAAQS, Congress directed the agency in the 1977 CAA Amendments to revise or reauthorize all of the NAAQS by Dec. 31, 1980, and every five years thereafter. The 1977 Amendments also required the Clean Air Science

[1] Primary NAAQS are intended to protect the public from known or reasonably anticipated adverse health effects with an adequate margin of safety. Secondary NAAQS are intended to protect public welfare from known or reasonably anticipated adverse effects on environmental and economic resources and personal well-being. However, this case study does not discuss the secondary NAAQS for particulates.

[2] The SAB was created by an administrative order in 1974 (Jasanoff 1990).

[3] The criteria air pollutants now include carbon monoxide, lead, nitrogen oxides, ozone, particulates, and sulfur oxides. According to an EPA official, the agency elected to schedule a revision of the ozone criteria first because the states "hadn't worked hard to implement" that NAAQS. SOx was included with PM because sulfate aerosols constitute a substantial portion of fine suspended particulate matter.

Advisory Committee (CASAC) to review the air quality criteria *and* standards and report directly to the Administrator *and* to Congress (Sec. 109, emphasis added).[4]

Litigation brought against EPA by the Iron and Steel Institute in 1978 was designed to keep the particulate review "in limbo," according to a former EPA official. But in October 1979, the agency announced that it was in the process of revising the Criteria Document for PM and SO_x and reviewing the existing NAAQS for possible revisions (44 *Fed. Reg.* 56731). In April 1980, EPA released for external review the first of three drafts of the revised PM/SOx Criteria Document, prepared by EPA Office of Research and Development Environmental Criteria and Assessment Office (ECAO) (45 *FR* 24913). From August 1980 to January 1981, EPA convened six public meetings of CASAC to review the CD, the second draft of which was released late in January (46 *FR* 9746). In the Spring of 1981, the EPA air program Office of Air Quality Planning and Standards (OAQPS) released the first draft of the Staff Paper (SP), a document informed by the Criteria Document and additional analysis which presents air program office staff recommendations regarding the NAAQS. In July and November of 1981, CASAC reviewed the second and third drafts of ECAO's criteria and the first and second drafts of OAQPS' staff analysis and recommendations.

In January 1982, a little over two years since EPA's initial announcement that the review was underway, CASAC sent a closure memorandum to the Administrator, Anne Gorsuch, indicating satisfaction with the final drafts of the CD and SP. Meanwhile, in order to make it clear that the agency would not use a particulates revision as a backdoor route to institute a regulatory acid rain program, PM and SO_x were decoupled administratively.[5] Reducing the scope of the review might have been expected to facilitate a timely decision; however, to comply with a 1981 Executive Order issued by the Reagan administration (E.O. 12291), EPA was now required to prepare an economic Regulatory Impact Analysis (RIA) on proposed major regulations for submission to the White House Office of Management and Budget (OMB).[6] In addition, no administrative action was politically feasible during the tumultuous period surrounding Gorsuch's 1983 resignation.

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[4] The 1977 Clean Air Act (CAA) Amendments authorized the Clean Air Scientific Advisory Committee (CASAC) to review all Criteria Documents prior to proposal and promulgation of national ambient air quality standards (NAAQS). The Environmental Research, Development and Demonstration Act (ERDDA) of 1978 gave statutory footing to the EPA Science Advisory Board (SAB) and also required that the SAB review the criteria and the NAAQS. Consequently, CASAC is administered by the SAB but has a distinct charter and independent status. In a provision which provides CASAC a broader scope of legitimate commentary than the rest of the agency's official science advisory committees, the 1977 Amendments authorized the Committee to advise the Administrator of "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." Not surprisingly, CASAC's exercise of its authority to comment on extra-scientific matters has been an episodic source of friction between the Committee and EPA.

[5] According to an EPA official, to do so, the agency would have had to institute a PM "cut value" of 3.5 microns, and indirectly implementing an acid rain program via the particulate standard would have been much more costly than a direct approach. In 1996, EPA proposed to revise the PM standard by adding $PM_{2.5}$ standards to the current PM_{10} standards (*Fed. Reg.*, Vol. 27, p. 1721).

[6] An estimated annual cost of $100 million was the threshold for "major" regulations under E.O. 12291.

In February 1984, EPA released an RIA for the particulates NAAQS, the monetized health benefits of which were based to a significant extent on epidemiological morbidity analyses.[7] A month later, the agency issued its notice of proposed rulemaking (49 *Fed. Reg.* 10408). On the same day, ORD's ECAO released a newly revised Criteria Document. Given the lag in EPA's review of the NAAQS for particulates occasioned by the change in administrations, the agency was appropriately concerned that its rulemaking would be susceptible to legal challenges that it did not "reflect that latest scientific [8] Already two years had passed since CASAC signed-off on the agency's scientific analysis. However, the Criteria Document also reinforced the notion that the epidemiological basis of the RIA was viewed with great skepticism by EPA's science analysts.

Some respondents suggested that the mistrust of regulatory analysis based on epidemiology was, at least in part, a manifestation of "CHESS Syndrome." The CHESS (Community Health and Environmental Surveillance System) research program began in 1967 under HEW's National Air Pollution Control Administration, and EPA inherited the program when the agency was created in 1970. In the public health tradition, CHESS collected ambient measurements and conducted epidemiological studies for criteria air pollutants. Problems with the CHESS program came to light when questions arose concerning a 1974 EPA study of SO_x. A 1975 SAB review of the study criticized both the epidemiological methods and presentation of the findings, and a series of 1976 *Los Angeles Times* articles alleged that EPA staff had deliberately distorted data to support their regulatory position. The news was followed by hearings and investigations by the House Committee on Science and Technology which concluded that the CHESS program at best served only to confirm previous scientific findings and that, as a result of inadequate peer review, the SO_x study was useless for regulatory purposes (Jasanoff 1990, pp. 84-86). As an EPA official recalls, "The Brown report [Rep. George Brown (D-CA), then chair of the House Science Committee] on the CHESS studies set the in-house 'epi' program back and tarnished the studies that were to be used in the early '80s. It clouded 'epi' studies in general, and the agency lost eight years of 'epi' work."[9]

In December 1985, CASAC concluded that relevant new studies had emerged over the preceding four years and recommended that the agency prepare addenda to the Criteria Document and Staff Paper. During 1986, addenda prepared by EPA analysts in ECAO and OAQPS were drafted, reviewed internally and externally, approved by CASAC, revised, and released (EPA 1986a,b). In July 1987, nearly 8 years after the

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[7] The principal economic analysis was prepared in 1983 by Mathtech for the EPA Economic Analysis Branch, OAQPS.

[8] American Iron and Steel filed suit in the U.S. Dist. Court, DC alleging that EPA did not use the latest science in the revised Criteria Document (*Inside EPA*, 5/11/84, p. 5).

[9] Although epidemiology has regained some credibility within the agency, several respondents characterized the agency's scientific culture as being dominated by experimental sciences such as toxicology, with observational sciences such as epidemiology and economics being subordinate. Note the debate in the arsenic in drinking water case study (Powell 1996) about the sufficiency of epidemiological evidence in the absence of supporting toxicological evidence.

agency announced the revision was underway, Administrator Lee Thomas signed the final rule (52 *Fed. Reg.* 24634). Table A-1 provides background for the development of national regulation and policy for ambient air particulates. Table A-2 provides a timeline of the 1987 NAAQS revision.

Table A-1. Background on US Regulation of Particulate Air Pollution.

1948	Air pollution episode in Donora, PA affects 40% of the town's population. Similar episodes occur in London and the US Eastern Seaboard over the next decades.
1963	Clean Air Act directs the Department of Health, Education, and Welfare (HEW) to prepare Criteria Documents (CDs) summarizing science on widespread air pollutants for use by state and local public health agencies.
1967	Air Quality Act specifies role of CDs in development of state air quality standards. National Air Pollution Control Administration initiates Community Health and Environmental Surveillance System (CHESS) research program.
1969	Surgeon General establishes National Air Quality Criteria Advisory Committee. Original Criteria Document for particulate matter (PM), measured in Total Suspended Particulates (TSP), produced by HEW.
1970	Clean Air Act Amendments call for National Ambient Air Quality Standards (NAAQS). EPA inherits national air pollution control authority and begins setting original NAAQS on the basis of HEW CDs.
1971	EPA promulgates original NAAQS for PM, setting a 24-hour level of 260 $\mu g/m^3$ and an annual level of 75 $\mu g/m^3$, measured in TSP.
1970s	Experimental findings indicate that TSP includes nonrespirable, coarse particles.
1976	EPA decides to revisit all of the NAAQS, with work scheduled to begin on a combined PM/sulfur oxides Criteria Document in 1979.
1977	Clean Air Act Amendments direct EPA to revise or reauthorize all of the NAAQS by Dec. 31, 1980, and every five years thereafter. The Amendments also establish the Clean Air Science Advisory Committee.
1987	EPA promulgates revised NAAQS for PM, setting a primary standard based on a 24-hour level of 150 $\mu g/m3$ and an annual level of 50 $\mu g/m^3$ using the PM_{10} indicator, which measures finer-sized particles than TSP.
1994	The Federal District Court of AZ orders EPA to review and, if necessary, revise the current NAAQS for particulates by January 31, 1997.
1996	EPA proposes to revise the current annual and daily PM_{10} standards by adding new annual and daily standards based on $PM_{2.5}$.

Table A-2. Timeline of the 1987 Particulate Matter NAAQS Revision.

1974	EPA air program begins investigating fine particle standard.
1979	EPA announces that it is in the process of revising the criteria document for particulate matter (and sulfur oxides), and reviewing existing air quality standards for possible revisions.
1980	April 11. Draft 1 of revised particulate matter/sulfur oxides criteria document (CD), prepared by ECAO, made available for external review August 20-22. CASAC public meeting to review draft 1 of CD. The committee recommends 5 additional public meetings be held at EPA to discuss the draft. Meetings held: November 7, 1980; November 20, 1980; November 25, 1980; December 4, 1980; January 7, 1981.
1981	January 29. CD Draft 2 released. Spring. First draft of Staff Paper prepared by OAQPS. July 7-9. CASAC public meeting to review Draft 2 of CD, Draft 1 of SP. October 28. CD Draft 3 released. November 16-18. CASAC public meeting to review Draft 3 of CD and Draft 2 of SP. December. Final draft of CD completed.
1982	January. CASAC closure memorandum endorses CD and SP. Final Draft of SP released. December. Final Draft of CD released.
1983	EPA Administrator Anne Gorsuch-Burford resigns.
1984	February. EPA releases Regulatory Impact Analysis. March. ECAO issues revised CD. March 20. Notice of Proposed Rulemaking (NPRM) proposes replacing TSP with PM_{10}, and a primary standard with a 24-hour level in the range of 150 to 250 $\mu g/m^3$ and an annual level in the range of 50 to 65 $\mu g/m^3$.
1985	December 16-17. CASAC meets to discuss relevance of new scientific studies on health effects of PM that emerged since the committee completed its review of the CD and SP in January, 1982. The committee recommends that the Agency prepare separate addenda to the CD and SP.
1986	May 22-23. Peer-review workshop at EPA (Research Triangle Park) to review First Draft of CD Addendum. July 3. External review draft of CD Addendum available. September 16. External review draft of SP Addendum available. October 15-16. CASAC public meeting to review Draft CD and SP Addenda. The SP and CASAC float reduced lower ends of the proposed ranges for the daily and annual levels (140 $\mu g/m^3$ and 40 $\mu g/m^3$, respectively.) December. CASAC sends closure memorandum on CD and SP Addenda to Administrator. Final CD and SP Addenda released.
1987	July 1. EPA promulgates final rule replacing TSP with PM_{10} and setting primary NAAQS levels at 150 $\mu g/m^3$ (daily) and 50$\mu g/m^3$ (annual).

The 1971 primary NAAQS for particulates, based on Total Suspended Particulates (TSP), included a daily (24-hour arithmetic) average of 260 $\mu g/m^3$ and an annual (geometric[10]) average of 75 $\mu g/m^3$. Experimental studies conducted by academics in the

[10] Because the geometric mean is less sensitive to extreme values than is the arithmetic mean, it is commonly used as an indicator of central tendency for asymmetric distributions such as the lognormal. The annual "geometric average" is lower than the arithmetic average and is less dependent on days with the highest recorded particulate levels.

late-60s and 1970s demonstrated that the fraction of PM that deposited deep in the pulmonary system (where particles may have adverse health effects) consisted of the smaller diameter components. EPA researchers recognized the implications: by regulating on the basis of TSP in 1971, "the agency realized it was missing the boat by measuring the wrong size category and having industry focus on the wrong size category," according to an EPA official. The 1984 proposal generated a range of alternative standards based on PM_{10}, a PM indicator focused on particles with a diameter of 10 microns or less: 150 - 250 $\mu g/m^3$ for the daily (arithmetic) average and 50 - 65 $\mu g/m^3$ for the annual (arithmetic) average. The 1986 Staff Paper Addendum included lower bounds for the daily and annual PM_{10} ranges, 140 $\mu g/m^3$ and 40 $\mu g/m^3$, respectively (1986b). In 1987, the final rule established the lower bound of the proposed ranges for both the daily (150 $\mu g/m^3$) and the annual (50 $\mu g/m^3$) levels of PM_{10}. New scientific findings, in the form of the particle deposition experiments, had penetrated the agency and initiated the long, complex sequence of revision.

Ultimately, the 1987 revisions do not appear to have appreciably tightened or relaxed the standard levels. Instead the result was a more refined targeting of pollution control and monitoring efforts on the finer-sized fraction of PM. In October 1994, seven years after the 1987 revision, a federal district court, in response to a suit brought by the American Lung Association, ordered EPA to review and, if necessary, revise the current NAAQS for particulates by January 31, 1997 (*ALA v. Browner*, DC AZ, 10/6/94). In November 1997, EPA proposed to revise the National Ambient Air Quality Standards for Particulate Matter on the basis of a slowly accumulated mass of epidemiological work (*Fed. Reg.*, Vol. 27, p. 1721). (See also Friedlander and Lippman 1994.)

2. Scientific Issues

Interviewees unanimously responded that overall there was adequate scientific information available in 1987 to inform the decision to revise the particulate NAAQS.[11] However, respondents identified a number of areas in which there was considerable scientific uncertainty, including: the specific constituents of particulate matter that were responsible for causing the observed effects; extrapolation between different ambient particle measures (i.e., British Smoke, TSP, PM_{10}) and from acute (high level, short duration) to chronic (low level, long duration) exposures; and interpretation of epidemiological studies utilizing subjective reported morbidity response data (e.g., restricted activity days). In terms of the overall magnitude of uncertainty, respondents' opinions varied markedly, although it seems that the most certain scientific issue was the implications of the studies demonstrating that smaller particles deposited more deeply in

[11] The unanimity of respondents, of course, should not be interpreted to mean that there were no dissenters in the scientific community. For example, some British scientists criticized EPA for using London mortality data associated with air pollution episodes to estimate human health effects at low particulate concentrations (e.g., Holland *et al.* 1979, cited in Friedlander and Lippman 1994). Some scientists and analysts affiliated with US industry (notably the electric power and steel sectors) also suggested that the uncertainties associated with quantitative risk assessments of particulates were too large to make them useful for regulatory purposes (e.g., Roth *et al.* 1986.)

the lungs. An EPA air program official commented that "there were many uncertainties. It's hard to know how they would combine quantitatively." The discussion below focuses on the determination of the appropriate particle size for the standard and on the consideration of the ambient particulate levels at which adverse health effects may occur.

Particle Size

Ambient particulate matter represents a broad class of chemically and physically diverse substances including liquid droplets or solids ranging in size from 0.005 to 100 microns.[12] On the basis of the 1969 HEW Criteria Document, EPA set the 1971 NAAQS using the TSP indicator of particulate matter. Aerometric TSP samplers vacuum suspended particles from the air and collect them in sizes up to 25-45 microns on filters (EPA 1982b).

According to an EPA official, air researchers recognized early on that TSP was a crude indicator because a variety of experimental dosimetry[13] results published in the late-60s and 1970s indicated that only particles much finer in diameter (on the order of 10 microns or less) were likely to deposit in the thoracic region, deep in the lungs (see, e.g., Albert *et al.* 1973, Lippman 1977).[14] Larger particles tend to be blocked or expelled from higher regions of the oronasal passages and thus would have minimal impact on lung function, respiratory ailments such as bronchitis, respiratory and cardiovascular disease, or mortality. In addition, atmospheric particles were shown to generally occur in a bimodal size distribution, with a fine fraction and a coarse fraction conventionally separated by a particle diameter of 2.5 microns (e.g., Whitby 1975).[15] On the weight basis used to set the particulates NAAQS in 1971, the large, non-respirable particles collected by TSP samplers dominated the smaller, respirable particles collected by the instruments.

Beginning in 1978, additional particulate depositional work was done at EPA by ORD's Health Effects Research Laboratory (HERL). Beyond synthesizing the accumulated literature, researchers at HERL conducted some original dosimetry work, and perhaps more importantly, connected the depositional results with the performance of aerometric sampling instruments to develop a recommended "cut value" for a revised particulates standard. A nominal, or 50% cutpoint refers to the particle diameter for which the efficiency of particle collection by sampling instruments is 50%. Larger particles are not excluded but are collected with decreasing efficiency (i.e., the larger the diameter of the suspended particle, the lower the likelihood of collection). A 1979 paper by HERL staff concluded that a cut value of 15 microns or less would ensure that the

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[12] 1 micron = 1 μm = 10^{-6} meters = 1 micrometer.

[13] Dosimetry refers to measurements of the dose of a chemical substance delivered to a specific organ in the body. The delivered dose can differ markedly from ambient concentrations to which people are exposed in rate, concentration, and kind (e.g., size fraction, metabolites).

[14] According to an academic researcher, the original depositional studies were conducted primarily at New York University (NYU) and Frankfurt, Germany. The NYU studies received early support from NIOSH and the American Medical Association but were primarily funded by NIEHS.

[15] Although the reference for Whitby (1975) reports EPA grant support, according to the EPA official, this work was funded by both EPA and the National Science Foundation (NSF).

NAAQS would focus on the inhalable fine fraction of suspended particulates (Miller *et al*. 1979).

Projections of areas that would fall into non-attainment for the particulates NAAQS without further controls were sensitive to the selection of the cut point, and the mining industry, whose emissions are predominately in the coarse fraction, argued for smaller cut points (e.g., PM_6). However, the issue was largely put to bed when, in 1981, the International Standards Organization adopted a nominal 10 micron cut point for particles that could penetrate the thoracic region (ISO 1981). Although technical support for the 10 micron level was based on the operating efficiencies of sampling instruments, rather than on any health basis, a former EPA official suggests that the argument for international harmonization of standards provided political cover for what was essentially a judgment call within the range below 15 microns. In 1984, the agency proposed to replace TSP with PM_{10}.[16]

Mortality and Morbidity

Having determined the particle size of concern, the next issue to be dealt with, as required under the Clean Air Act, was to determine the ambient concentration of PM_{10} at which no reasonably expected adverse health effects would occur, including an allowance for an adequate margin of safety, and taking into consideration sensitive members of the population. However, this legislative framing of the issue presumes that there exists an identifiable threshold level below which no adverse effects occur. "This is the problem with ambient air quality standards," concludes a former EPA researcher. "What you're trying to do is ludicrous--set the level below which the most sensitive person in the population will have no adverse health effects. In fact, it is impossible to come up with a scientifically justifiable number. The only intelligent way is cost-benefit or cost-effectiveness analysis, but we don't do that." Saddled with a scientifically unsound congressional mandate, EPA undertook to determine the lowest levels of PM_{10} at which mortality and morbidity effects could be detected or reasonably inferred.

The EPA HERL and other laboratories conduct clinical studies of humans in environmentally controlled exposure chambers, and numerous chamber studies were conducted for PM/SO_x prior to 1987 (see EPA 1982a, 1986a). However, the experimental conditions lack generalizability, in particular to chronic exposures, and the subjects employed are often healthy adults not representative of sensitive populations at risk: the elderly, those with pre-existing conditions, and children.[17] According to some respondents, toxicological experiments with laboratory animals provided very clear mechanistic support for the adverse effects of SO_x aerosols in animals. Furthermore, dosimetry work helped researchers bridge the gap between the toxicological findings in animals and the chamber study results in humans. However, unlike most pollutants, PM is

[16] In a letter sent to EPA Adm. Carol Browner after reviewing the first draft of EPA's 1995 Staff Paper for PM, CASAC Chairman George Wolff reported that several CASAC members "felt that the selection of a
Risk Policy Report, 1/19/96, pp. 5-6).

[17] Some SO_2 chamber studies were conducted with asthmatics, however.

defined by its size; it is not chemically specified or even associated with a particular industrial process.[18] The effects of toxicological experiments with inhaled particulates depend largely on their chemical composition, which varies considerably in the environment. As a result, "the toxicological basis for particulates is weaker than for other criteria air pollutants," according to an EPA air program official.

Given the limits of experimental data in determining "safe" particulate levels, analysts turned to epidemiology to establish associations between observed mortality and morbidity in populations exposed to measured ambient particulate levels. Three sets of epidemiological studies are noteworthy. Studies of London mortality data, which were relevant to acute exposures; the Harvard Six City study, which was primarily relevant to chronic exposures;[19] and a final set of studies (which were questioned by health scientists but included in the economic RIA) relating chronic particulate exposures to reported morbidity measures.

For the purposes of setting regulatory levels of PM_{10}, most attention was focused on studies which would influence the daily standard because it was generally considered to drive the annual standard. Considering the 24-hour and annual standards together, for example, EPA (1986b) projected that attaining a 24-hour standard of 150 $\mu g/m^3$ would substantially reduce annual average levels in a number of areas to below 50 $\mu g/m^3$. Analyses of London mortality data had been accumulating in the literature for more than 20 years at the time of the PM review (e.g., Martin and Bradley 1960), but transfer of the results to the US was frustrated by the incomparability of British and US air pollution measures. The British smokeshade (BS) indicator analyzes light reflected from a stain formed by particulate matter collected on paper. The collection equipment typically employed had a cutpoint of approximately 4.5 microns (EPA 1982a). Unlike the TSP or PM_{10} measures, the BS method did not permit direct measurement of the weight or chemical composition of collected particles. Instead, it reflected the density of the stain and the optical properties of the collected materials. As a result, the BS method was a better measure for sooty dark particles, such as elemental carbon, than for aerosols, such as sulfates.

In the 1980s, academic epidemiologists, EPA policy analysts, and others re-analyzed the London data (e.g., Mazumdar *et al.* 1980; Ostro 1984; Schwartz and Marcus 1986). The re-analyses suggested the lack of a threshold in the relationship between "British smoke" levels and mortality. The conundrum of comparing incomparable measurements was bypassed by re-analyzing the London data on its own merits. "Nobody

[18] An illustration of the latter would be whole effluent testing, which applies aquatic toxicology to an unspecified waste stream originating from a specified process, such as leather tanning.

[19] In addition to the chronic exposure study discussed below, the Harvard Six City Study also included investigations of reversible declines in lung function in children associated with acute exposures (Dockery *et al*. 1982). Only the acute study was longitudinal in design, meaning that the study population was observed over time. The chronic study was cross-sectional in design, meaning that the health status of the study population observed at one particular time was related to their estimated chronic exposure levels.

knew how to convert from BS to PM-10," allows a former EPA analyst, "but the lack of a threshold was clear, or if there was one, it clearly went down to very low levels."

There remains some uncertainty in exporting the results, however, as a consequence of the differences in composition of particulate matter between London, ca. 1958-72 (with soot from coal use) and contemporary US cities where particulates of concern are predominately aerosols and fine dusts. Mortality studies conducted solely on the basis of epidemiological data in contemporary US cities, however, suffer from an inability to tease the potentially independent effects of particulates apart from the potential contributions of other air pollutants which may be correlated with PM, such as ozone and SO_x. In addition, it is uncertain to what extent the relationship between mortality and acute air pollution exposures reflects the death of previously ill people whose lives may be shortened by a matter of days or weeks, the ghoulishly dubbed "harvesting effect."

The Harvard Six City Study (Ware *et al*. 1986) found that increased rates of bronchitis and lower respiratory illness in preadolescent children were associated with annual average ambient fine particulate concentrations. In addition to their focus on a biologically sensitive--and politically salient--subpopulation, the relevance of the Harvard study results was that the effects were neither associated with historic episodes of gross air pollution nor observed in Europe, but were observed at concentrations experienced in eastern and midwestern US cities between 1974 and 1977.[20]

A series of epidemiological studies by economists and policy analysts developed quantitative relationships between chronic ambient particulate exposures and morbidity effects for which monetary values could be readily attributed (e.g., Lave and Seskin 1977; Ostro, 1983). According to a number of respondents, these studies tended to suggest net economic benefits at levels of particulates lower than current standards. However, experimental scientists had numerous objections to relying on these studies for quantitative assessments of the health impacts of different ambient PM_{10} concentrations. For example, the studies utilized air monitoring data available from networks established for determining area-wide attainment of NAAQS. Such monitoring data is often poorly correlated with actual human exposures within the area, and in addition, most of the PM data were measured in terms of TSP rather than PM_{10}. While concurrent TSP and PM_{10} measurement was initiated in the 1980s on some monitoring sites in some cities to facilitate eventual conversion between the indicators, the relationship between TSP and PM_{10} can vary markedly among sites. For the majority of monitoring sites without concurrent TSP and PM_{10} measurements, any estimated relationship between "backcasted" PM_{10} exposures and reported morbidity effects was therefore highly uncertain.

In addition, these studies used indicators of morbidity that were economically relevant and available over a broad range of areas and exposure levels, such as responses

[20] The six cities included in the study were: Steubenville, OH; Watertown, MA; Portage, WI; Topeka, KA; St. Louis, MO; and Harriman, TN. The Harvard study received support from NIEHS, EPA, and the Electric Power Research Institute (EPRI).

from the National Health Interview Survey.[21] Such surveys include questions like, "did you go to work today?" Without some formal calibration (which could be achieved by conducting a follow-up, independent confirmation of the accuracy of responses for a subsample of the survey), the reliability of survey data is hard to assess. Evaluating subjective "ordinal" responses from different individuals is also problematic (for example, the same response to "is your cough severe or mild?" from different people can mask substantial differences in the severity of symptoms). Experimental scientists are generally skeptical of data they regard as "subjective." But by relying on overt "clinical" symptoms associated with acute exposures, analysts may not capture important health effects resulting from "real world" exposure levels and patterns. A senior EPA careerist stated that the epidemiological analysis conducted by economists and included in the RIA "was not sufficiently developed or broadly accepted." ECAO's Criteria Document gave the Harvard Study a generally favorable review but concluded that few of the studies on morbidity effects associated with chronic exposures to airborne particles provided useful results by which to derive quantitative conclusions concerning exposure-effect relationships (EPA 1986a).

Regarding the epidemiological evidence overall, responses from the interviewees were mixed. Some respondents characterized the epidemiology available for the 1987 PM revision as good-to-very good, but a former EPA researcher judged that "the 'epi' was only fair. The methods were underdeveloped, even for their time. Very few of the studies controlled for confounding variables."[22] According to a statistical analyst, "epi, dose-response studies are simply hard to carry out. There's always going to be different interpretations with these types of studies. Some of it points this way; some of it points that way. There are not enough scientists, time, and money to come up with definitive answers." As a result, controversies over such studies generally boil down to differing judgments about what constitutes sufficient evidence in the context of a specific decision. These judgments will invariably be conditioned by underlying values.

3. The Process within EPA

Setting the Agenda

The legislative mandate for revisiting NAAQS on a five year cycle was the factor most frequently (6) mentioned by respondents as being responsible for getting the PM revision on the agency's agenda. However, activity within the agency began at least three years prior to the 1977 CAA Amendments. One air program official "came into the agency in 1974 to look into a fine particle standard." Despite the legislative requirement

[21] See Adams *et al*. (1984) for a discussion of the tradeoffs for environmental decisionmaking between replications at particular exposure levels and coverage over the range of exposures. In sum, replication contributes to the precision necessary to discriminate the rank order of the distribution of net benefits under a limited set of policy alternatives, but without adequate coverage to reduce model uncertainty, the magnitude of the net benefits remains uncertain.

[22] Confounding variables are alternative, uncontrolled factors that may account for variation in the observed effects--for example, the potential effects of ozone and SO_x discussed above.

for periodic review, in the view of a former agency political appointee, "What got the decision on the agency's agenda was the depositional studies." Therefore, new scientific information played a key role in setting the regulatory agenda.

Most of the early activity within EPA occurred in Research Triangle Park, NC where air program offices (OAQPS) and research offices (ECAO and HERL) are co-located. A 1974 paper by John Bachmann in the air program's OAQPS addressed the question of whether sulfates should be regulated separately from the rest of suspended particulates. Four years later, OAQPS requested that ORD's ECAO begin to address the issue of particle size and the appropriate cut value for monitoring equipment. In 1979, Fred Miller, who previously had been conducting academic research on ozone dosimetry, and others at HERL made the recommendation to set the nominal cut point at 15 microns or less.

The Criteria Document-Staff Paper Process

As detailed in the background section above, ECAO and OAQPS spent much of the next 7 years drafting, vetting, and revising Criteria Documents and Staff Papers for the PM revision. Much of the writing of the Criteria Documents for PM was contracted out to academics and independent researchers. But with the exception of some of the exposure assessment work which was contracted, the Staff Papers, according to an air program official "were basically a 4 person effort" conducted by OAQPS staff. A number of respondents commented that the practice of relying on contracted experts to contribute to Criteria Documents can result in authoritative but unsynthesized analysis. But ECAO resources are insufficient to maintain a cadre of full-time staff dedicated to each criteria air pollutant.[23]

While EPA drafted and revised CDs and SPs, the agency's stated intention to replace the TSP measure motivated others outside the agency to conduct additional dosimetry work (which according to an EPA air program official confirmed earlier findings) and ambient air monitor manufacturers to develop alternative sampling technology. During the course of the ongoing scientific review, the agency also initiated simultaneous monitoring of PM_{10} and TSP in several areas. An academic remarked, "Give the agency credit for gathering that data prior to finishing the review. The agency set about to create research networks in numerous cities to make scientifically valid conversion factors, investing in the resources to get the necessary data. It was started too late if they were going to [finalize the rule] by 1985, but it was in time for 1987."

Early in the review process, EPA staff also approached Harvard investigators about conducting the "Six City" study. The agency was motivated to support the research

[23] According to a former EPA air program official, the cost to EPA of developing a NAAQS is in the $4-8 million range. This estimate may not reflect, however, the cost associated with EPA research (in-house and extramural) that contributes to the foundation of the standard. ECAO and OAQPS also have increasing demands on their resources for conducting risk analyses for Hazardous Air Pollutants as a result of the 1990 Clean Air Act Amendments.

because prior epidemiological studies came from the field of occupational health which did not cover potentially sensitive or highly exposed populations such as children, the elderly, or outdoor laborers. According to an EPA air program official, the Harvard study represented an early model of environmental regulators "posing questions that the scientists had not previously asked." Combining support from EPA, NIEHS, and EPRI, the Harvard group began issuing a series of reports on or about 1981 that provided input into the PM revision (e.g., Ware *et al.* 1981). Due to the length of the PM review period, the Harvard group was able to produce some answers to regulators' questions prior to the decision, a rarity for multi-year, complex epidemiological studies.

According to an EPA official, OAQPS requested that Joel Schwartz, an analyst in the agency's Office of Policy Analysis (OPA), conduct a re-analysis of the British mortality data. Previous re-analyses had been conducted, including one by OPA's Bart Ostro (Ostro 1984), but Schwartz and Marcus (1986) addressed a number of methodological questions raised by reviewers. This re-analysis carried considerable weight. According to an EPA official, "Schwartz had clout because he was smarter than everybody else." (Schwartz had also established some credibility with CASAC on the strength of his work on the effects of lead air pollution. See Powell (1996).) Access to the raw British mortality data was also a key factor that permitted Schwartz and Marcus to address the reviewers' questions. In the majority of cases, EPA regulatory analysts do not have access to raw data. Currently a biostatistician in ECAO, Marcus "was pleasantly surprised that they were able to get the raw data... It made me optimistic that in-house researchers could do just as good a job as PIs [principal investigators] and extract the information that was relevant to the agency. Now I find that's not always the case." Even when the agency is able to gain access to the raw data, says Marcus "we generally don't have the time and resources to redo the analysis to make sure that [the original investigators] did it right."

The proximity of ECAO and OAQPS to each other, the frequent circulation of personnel between the offices, and their detachment from Headquarters offices in Washington, DC have resulted in a level of inter-office coordination that, although not without tensions, is uncommon within the agency. On the downside, according to a senior careerist, the close arrangement can sometimes "discourage debate." As an illustration, this EPA official points to the acquiescence to ECAO's critique of much of the epidemiological evidence. Another factor that may have contributed to curtailing substantive debate was tension between the air program headquarters and OAQPS. According to an EPA air program official, early in the 1980s headquarters was complaining, "we're constantly pulling buckshot out of our ass" for failing to make revisions more quickly. Reflecting a typical face-off between careerists and politicos, "DC felt that OAQPS was hard-headed, not dealing with DC as a client. RTP [Research Triangle Park] said 'we know what we're doing.'" According to respondents, headquarters dispatched Gerald Emison to be the new Director of OAQPS in 1984 "to make sure the trains run on time."

Respondents all characterized the agency's treatment of the scientific information available at the time of the decision to revise the PM standard as good-to-very good. However, an academic provided a qualified endorsement. "It was very good in terms of the best that can be done, and very poor in terms of not having enough data. EPA doesn't support any research to speak of, so they have to find information available from studies with other objectives. They're skillful in taking what information is out there and drawing inferences from it, but the data are very weak. The agency has never put enough effort into generating sufficient data."

Communicating the Science to Agency Leadership

Respondents rated the communication of the scientific information to agency decisionmakers as good-to-very good. EPA staff briefed three successive Administrators. In a meeting that was kept secret from most of the agency, staff briefed Administrator Anne Gorsuch prior to her resignation, according to an air program official. Reportedly, the benefits analysis included in the RIA prevented Gorsuch from relaxing the standard. Administrator Ruckelshaus was initially briefed in 1983 and later received a two-day briefing. However, agency leaders believed that data at that point were inadequate and questioned why a research strategy had not been laid out and conducted in advance to provide a better database for the eventual review of the standard. Why, for example, had sensitive populations not been addressed? According to a former EPA official, Administrator Ruckelshaus's concern that CASAC had not endorsed a specific level for the PM_{10} standard led to the unprecedented decision to propose a range for a NAAQS.

As is generally the case, the majority of the communication of scientific information to agency decisionmakers was conducted orally or through brief memos. However, Al Alm, Ruckelshaus' Deputy Administrator who was described as "a voracious reader," was supplied with a stream of materials prior to the proposal in 1984. Alm and Assistant Administrator for Air Joseph Cannon were also briefed on the benefits analysis, and according to an air program official, "it helped justify going to the lower bound of the proposed range in their minds." Finally, Lee Thomas was briefed prior to issuing the final rule in 1987.

There were a number of key agency staff involved in the briefings, including Bruce Jordan, the OAQPS Ambient Air Standards Branch Chief and ECAO's Les Grant. During his tenure in the Ruckelshaus administration as Assistant Administrator for ORD, Bernard Goldstein was also influential in translating and interpreting the science for agency decisionmakers. But in each case, John Bachmann, the lead author of the OAQPS Staff Papers, was the principal staffer responsible for communicating the science to the leadership. In his role as lead author of the SP, Bachmann served as the bridge between ECAO and OAQPS. Bachmann was also responsible for preparations for the lengthy series of CASAC meetings. Respondents remarked that Bachmann was an effective communicator because straddling the science-policy divide, he grasped the relevance of the scientific findings, and he could talk about the science to decisionmakers in simple terms without jargon.

Regarding the PM revision, an air program official noted, "The process took a long time from proposal to finalization. In terms of key players, it was like a conveyor belt." Over the entire life of the review, there was not only a change of the guard in the Administrator's Office but also turnover at senior political and administrative levels. Between the proposal and final rulemaking, there was turnover in the air program at the Assistant Administrator level, from Joseph Cannon to Craig Potter, and the directorship of OAQPS changed hands from Walter Barber to Gerald Emison. But careerists such as Bachmann, Grant, and Jordan were constants. While agency careerists may retain a regulatory issue in their portfolio for several years, if not their entire careers, the tenure of senior political appointees in the federal government is generally on the order of 2 or 3 years. Therefore, even if EPA were to comply with the 5 year review cycle for NAAQS, significant turnover of politically accountable decisionmakers would be likely. As a result, policymakers are often dependent on careerists for information, and careerists often have to make allowances for bringing new political appointees up to speed.

The Role of External Scientists in the Process

All respondents characterized the role of non-agency scientists in influencing the PM revision process as significant-to-very significant, and there was a consensus that non-agency scientists also played a significant role in legitimizing the agency's decision. However, the influence was not entirely positive. A former EPA researcher argued that the scientific review process was "protracted by a conscious decision to have the adversaries present" at agency working sessions. Some of this input may have served little more than to strengthen the agency's record of decision. On the other hand, some agency officials believed that industry analysts, from the electric utility sector for example, helped "sharpen the agency's analysis" and prompted the agency to "slay those dragons which can be slain." It appears that industry input into the agency's analysis for setting the NAAQS levels may have contributed more than industry analysis regarding the determination of the particle size cut value.

As detailed in the background discussion above, CASAC played an extensive role in the PM review process. There was considerable continuity between the 1982 and 1986 panels. One of the members served on both panels, and four of the 1986 members had served as consultants to the 1982 panel, including Morton Lippman, Chair of the 1986 panel.[24] Lippman had also been a principal researcher involved in the particulate deposition studies responsible for getting the PM revision on the agency's agenda.

EPA analysts were confronted with a lack of official agency guidance for conducting NAAQS reviews in particular and for non-cancer risk assessments in general. As a result, respondents noted that the agency "sought CASAC endorsement of what they were doing" methodologically to ensure scientific credibility and acceptance. For

[24] The member who served on both panels was Mary Amdur of MIT. Edward Crandall of Cornell, Timothy Larson of U. of WA, and Roger McClellan of the Lovelace Research Inst. served as consultants in 1982 and members in 1986.

example, a critical area where there was no generally accepted scientific method was converting measurements between TSP and PM_{10}, so the agency relied on CASAC review and endorsement to ensure the credibility of its conversions. Apart from methodological review, CASAC also played a role regarding the NAAQS levels finally adopted by EPA. The entire range for the standard proposed by the agency in 1984 (150 - 250 $\mu g/m^3$) was intended, in the words of an EPA official "to be protective of public health."

At its 1986 meeting, however, CASAC suggested that the agency adopt the lower end of the proposed range and even consider going below it in order to provide a greater margin of safety. Although the adequacy of the margin of safety is generally regarded as an issue in the policy domain, providing such advice seems well within CASAC's statutory authority to comment on standards as well as the criteria. According to one former EPA official, CASAC suggested that EPA consider a standard below the proposed range to provide the agency with cover to justify promulgating the standard at the lower bound of the proposed range (150 $\mu g/m^3$). If this account is accurate, one could reasonably argue that engaging in this type of strategic behavior exceeds CASAC's legislative authority to advise and comment on agency criteria and standards. However, it should be noted that the 1986 Staff Paper also included reduced lower bounds of the range. Another former EPA official says that CASAC Chair Lippman's view was that the upper end of the proposed range provided little, if any, margin of safety and the rest of the committee deferred to Lippman's expertise.

4. Science in the Final Decision

In 1987, the final rule established the lower bound of the proposed ranges for both the daily (150 $\mu g/m^3$) and the annual (50 $\mu g/m^3$) averages for the PM_{10} NAAQS. An EPA official commented, "Without CASAC endorsement, the agency would be concerned about the credibility and legal defensibility of the decision." However, CASAC's role should not be overstated. In issuing the proposal in 1984, Administrator Ruckelshaus acknowledged that he leaned towards primary standards from the lower portions of the proposed ranges. Respondents also suggested that OAQPS staff and ECAO's Lester Grant recommended setting the daily standard at 150 $\mu g/m^3$. Finally, according to an air program official, "One thing a decisionmaker doesn't want is to be surprised by studies that are going to come out [after the decision]." In the case of the PM revision, agency leadership "was told at the time that there would probably be studies forthcoming suggesting concern at even lower levels."

> *at the time that there would probably be studies forthcoming suggesting concern at even lower levels."*

Respondents rated the level of consideration given to the scientific issues by agency decisionmakers as thorough-to-very thorough, and there was a consensus that the scientific information had a high impact on the ultimate decision. The minds of agency leaders were focused because of the economic stakes involved in the PM NAAQS. EPA (1986c) estimates compliance costs of more than $500 million per year. (The threshold for a "major" regulation is $100 million per year.) A senior EPA careerist noted,

Administrator Lee Thomas "put a lot of time into it," and an air program official recalled, "Lee Thomas had a lot of questions." According to an air program official, the reason the "communication [of the scientific information] was so good was because decisionmakers spent a lot of time trying to understand what the issues were." Despite focusing considerable attention on the scientific issues, according to a former EPA official, "Thomas was given a very narrow range of staff recommendations; he was given little

Respondents pointed to a scattering of factors that impeded the use of science in the PM revision, with no one factor being mentioned more than twice. However, grouping the problems as follows suggests that respondents believed that the major impediments were associated with the data and methods and the problems of matching science with policy.[25]

- Problems with the Data and Methods (7): large scientific uncertainties (2); inadequate epidemiological and toxicological tools and methods (2); the large volume of information available; the lack of relevant information; the lack of EPA funding for research.

- Problems Matching Science with Policy (5): the CAA's presumption that a pollutant concentration exists below which there are no adverse health effects; scientists lack understanding of policymakers' information needs; policymakers perceive staff scientific analysis as deficient due to the quality of EPA staff; EPA policymakers lack understanding of what science can contribute to decisionmaking; the adversarial rulemaking process.

- Problems with Disciplinary Science (2): disciplinary inertia prevents consideration of new scientific findings; disciplinary boundaries result in fragmented, narrow analyses.

Peer review (both internal and external) was the factor most frequently mentioned by respondents as facilitating the use of science in the PM revision (6). Other factors included the skill of EPA staff (2); the high economic stakes; the clear health basis of the NAAQS under the CAA; the legislative requirement for periodic revision of the NAAQS; and good communications between scientists and policymakers.

5. Concluding Observations

More than ten years before EPA proposed to revise the NAAQS for particulates, the narrowly-scoped results of new particle deposition experiments had penetrated deep into the agency, far removed from decisionmakers in Washington. The findings initiated a long, complex sequence of activity that was promoted and inhibited by multiple factors. A key air office staffer, John Bachmann was primarily responsible for transferring the

[25] Numbers in parentheses refer to the frequency with which a factor was mentioned by respondents as impeding or facilitating the use of science.

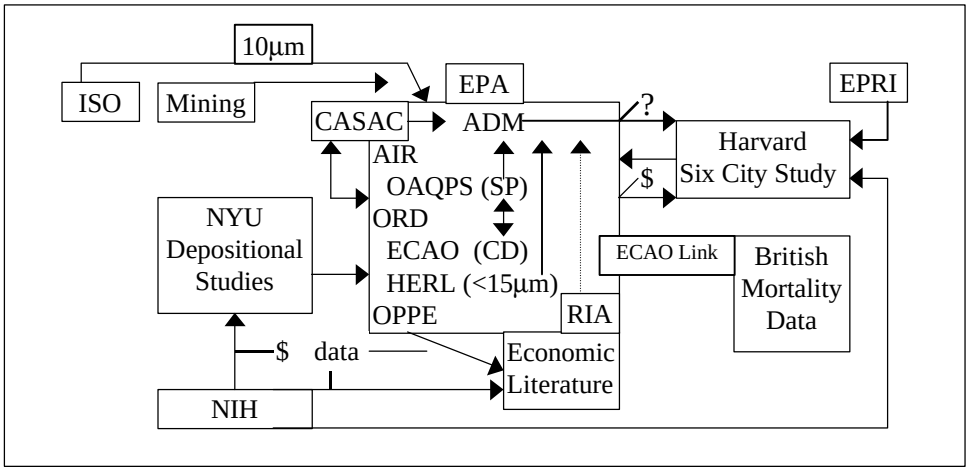
accumulating scientific information from the researchers through the air program and finally to politically accountable decisionmakers.

The primary source of support for the depositional studies conducted by NYU researchers was NIEHS. Agency staff in Research Triangle Park dedicated to surveying the scientific literature for new, relevant information were exposed to the information and grasped its significance. However, additional work was needed to transform the depositional findings into an operational cut value for use in the design of air pollution monitoring equipment and for setting the NAAQS. Much of this supplementary work was conducted within EPA by researchers at HERL. The mining industry attempted to influence the agency's use of the information to further reduce the cut size, but the International Standards Organization's position was operationally practical and provided political cover. EPA adopted the PM_{10} indicator.

Due to the lengthy review period, Harvard researchers, supported by NIEHS, EPA, and EPRI were able to provide information prior to the final decision regarding the effects on sensitive populations of particulate matter not at levels associated with acute episodes in foreign lands, but at typical concentrations experienced in U.S. urban areas. This study was prompted by questions posed by environmental policymakers, not by the scientific community. A reanalysis of the British mortality data requested by OAQPS and conducted by an EPA policy official suggested the lack of a discernible threshold in the relationship between particulate levels and mortality. EPA was able to access the raw data due to international linkages established by ECAO. Both of these studies were evaluated favorably by EPA scientists and CASAC and provided scientific support for adopting levels of the PM_{10} standards at the lower ends of the proposed ranges.

The epidemiological morbidity studies originating from the economic literature, however, experienced a slightly different fate. These studies were based on available monitoring and health survey data that enabled researchers to evaluate health effects in economically relevant terms. In this case, the internal receptor and promoter within the agency was the Office of Policy Analysis. ECAO and CASAC, acting in their science gatekeeper role, rendered these studies somewhat impotent. Officially, EPA concluded that too many fundamental questions remained considering the RIA methodology, and in any event, the CAA did not permit the consideration of costs in setting the NAAQS. Unofficially, according to respondents, the RIA's projection of net benefits at levels below the proposed range for PM_{10} helped justify the final decision by the Thomas Administration to select the lowest end of the range and prevented the Gorsuch Administration from relaxing the NAAQS. Therefore the economic analysis appears to have indirectly influenced the outcome toward the same end as scientific analysis. Irrespective of the impact the information had on the decision, this case study illustrates how, in the context of a single decision, different organizations and disciplines within EPA use different sources of scientific information for different purposes and judge the information by different criteria. Figure A-1 illustrates the fate and transport dynamics of these key sources of scientific information in the 1987 PM revision.

Figure A-1. Fate and Transport Dynamics for Science in the 1987 Particulate Matter Revision.



In the course of discussing the 1987 PM review, a number of respondents expressed frustration with the Criteria Document-Staff Paper process in general. The most frequently mentioned source of the problem was ECAO's practice of developing voluminous CD's. However, respondents also noted that while CASAC has called for more succinct CD's, individual panel members display a tendency to strive to ensure that the documents cover their own disciplines in exhaustive detail. Whether, in any particular case, this is "just academics being academics," as one respondent put it, or strategic behavior intended to keep their discipline high on the environmental research agenda can not be determined.

Another criticism of the process was that ECAO and the air program appear reluctant to work on more than one criteria pollutant at a time. Again, a number of factors may be at play. According to an academic researcher, ORD management has not made Criteria Document development an organizational priority, and ECAO Director Les Grant's direct involvement as a principal author also may limit the number of criteria pollutants that can be addressed at any given time. The air program, in turn, is reluctant to focus on more than one pollutant at a time because doing so would increase the burdens on state officials and EPA program staff in terms of developing and reviewing State Implementation Plans for NAAQS attainment. There may also be a mismatch in terms of ECAO staffing. Although NAAQS are increasingly driven by epidemiological findings, most agency scientific staff have backgrounds in toxicological and other experimental sciences. Relatively fewer have backgrounds in epidemiology and statistics.

This case study provides an illustration of non-agency scientists operating in multiple, overlapping roles. Three out of seven of the contributors to the 1982 Criteria Document epidemiological chapter were from the Harvard Study group (Benjamin Ferris, Frank Speizer, and James Ware). Ware later served as a member of CASAC in 1986. It is not uncommon for scientists to provide evidence as academic researchers, contribute to

assessments as contractors, and evaluate results from a position on an independent advisory committee. In part, this reflects the small number of expert practitioners in highly specialized areas. On the other hand, it poses the risks associated with insularity and inbreeding.

Epilogue: Regarding the current PM review, an air program official noted that the Criteria Document and Staff Paper process, which extended over many years and occurred sequentially in the 1987 revision, has been compressed and run in parallel under the court-ordered deadline. Although the CD has been widely faulted for being too long and unfocused, this official suggested that it is sometimes hard to predict what the OAQPS staff and CASAC will regard as critical. In prior reviews the first draft of the CD was revised while the SP was being developed, providing a feedback loop in the process of reviewing and interpreting the scientific information. The court-ordered deadline has the effect of eliminating or crimping this feedback loop. CASAC also bridled at the compressed review schedule which only permitted the Committee a single opportunity to review the CD and SP in draft. (After EPA proposed to revise the NAAQS for PM in November 1996, the agency announced that it would convene a meeting of CASAC to enable the committee to comment on the proposals (*Inside EPA*, 12/20/96, p. 10.)

In March 1996, CASAC Chair George Wolff sent Administrator Carol Browner a consensus closure letter regarding the new Criteria Document for Particulate Matter. In the letter, Wolff reported that "about half of the Panel members expressed concern that the case made in the Criteria Document for $PM_{2.5}$ being the best available surrogate for the principal causative agent in PM_{10} may be overstated, and that EPA has not adequately justified its rejection of other alternative explanations..." However, Former CASAC Chair Morton Lippman and three other CASAC members took the rare step of sending Browner a "supplementary" letter contending that: there is sufficient evidence of a causal relationship between PM exposure and excess mortality and morbidity; $PM_{2.5}$ is better than any alternative measure; and because some adverse health effects may be linked to coarser particles, separate fine (i.e., $PM_{2.5}$) and coarse (i.e., PM_{10}) standards should be considered (*Risk Policy Report*, 4/19/96). Shortly after the elections of November 1996, EPA proposed to supplement the current primary PM_{10} standards by adding two new primary $PM_{2.5}$ standards set at 15 $\mu g/m^3$, annual mean, and 50 $\mu g/m^3$, 24-hour average (*Fed. Reg.*, Vol., 27, p. 1721). Given CASAC's importance in legitimizing EPA's NAAQS decisionmaking, it remains to be seen whether the agency can or will revise the standard without the panel's unanimous endorsement.

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LIST OF ABBREVIATIONS

BS	British smokeshade
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee, EPA
CD	Criteria Document
CHESS	Community Health and Environmental Surveillance System
ECAO	Environmental Criteria and Assessment Office, EPA
EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
HERL	Health Effects Research Laboratory, EPA
HEW	Department of Health, Education and Welfare
$\mu g/m^3$	micrograms per cubic meter
NAAQS	National Ambient Air Quality Standard
NIEHS	National Institute of Environmental Health Sciences
NYU	New York University
OAQPS	Office of Air Quality Planning and Standards, EPA
OMB	Office of Management and Budget, The White House
OPA	Office of Policy Analysis, EPA
PM	particulate matter
PM10	particulate matter, 10-micron diameter
PM2.5	particulate matter, 2.5-micron diameter
RIA	Regulatory impact analysis
RTP	Research Triangle Park, North Carolina
SAB	Science Advisory Board, EPA
SO_x	sulfur oxides
SO_2	sulfur dioxide
SP	Staff Paper
TSP	total suspended particulate

B. The 1993 Decision Not to Revise the NAAQS for Ozone

1. Background

Health effects from ambient levels of tropospheric ozone were first reported in 1967 in terms of lowered performance by high school athletes in California on high-exposure days (Lippman 1991). Since then, regulation of tropospheric ozone has unfolded slowly, despite a legislative requirement for periodic review, and been characterized by discord and litigation. The role of science and scientists in the ozone standard setting process has increased and become more formal over time. But this has not diminished the controversy, in large part, because the Clean Air Act is based on the false scientific premise that a threshold level exists below which health effects from ubiquitous air pollutants will not be observed. As a consequence of this mistaken legislative presumption, new scientific developments inevitably point toward ever more stringent ambient ozone standards and preordain--in principle--the outcome of periodic reviews of the scientific basis of ozone regulation. In practice, EPA's response has been to delay the inevitable.

The National Ambient Air Quality Standard (NAAQS) for all photochemical oxidants was originally set in 1971 at a maximum hourly average of 0.08 ppm (parts per million), not to be exceeded more than once per year.[26] According to a former EPA political appointee, science played little role in the initial ozone NAAQS.[27] "[Former Senator Edwin] Muskie [D-ME] wanted a 95% reduction—that was his goal." The principal scientific rationale for the 1971 standard was one study which reported that asthmatics had more attacks on days when ozone levels were above 0.10 ppm. A subsequent reassessment of the study revealed that the actual exposure levels were considerably higher (Landy *et al*. 1994). In 1976, the American Petroleum Institute (API) and the city of Houston petitioned EPA to revise the standard (Marraro 1982). Consequently, EPA initiated a review of the NAAQS for Photochemical Oxidants in 1977 (McKee 1994).

In 1978, EPA finalized the Criteria Document (CD, an assessment of the available scientific information regarding health and welfare effects) for photochemical oxidants and proposed to revise the NAAQS. The agency proposed to: 1) raise the primary NAAQS to 0.10 ppm and retain the secondary NAAQS of 0.08 ppm;[28] 2) measure and enforce the standard using tropospheric ozone as the chemical indicator species for the family of

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[26] Photochemical oxidants are a class of highly reactive gases which includes ozone (O_3). They occur in the troposphere (ground-level atmosphere) and are formed in chemical reactions that occur in the presence of sunlight. Stratospheric ozone, on the other hand, occurs higher in the atmosphere and filters ultraviolet radiation.

[27] The 1970 Clean Air Act gave EPA 90 days to propose six NAAQS.

[28] Primary NAAQS are intended to protect the public from known or reasonably anticipated adverse health effects with an adequate margin of safety. Secondary NAAQS are intended to protect public welfare from known or reasonably anticipated adverse effects on environmental and economic resources and personal well-being.

photochemical oxidants;[29] and 3) change the form of the standard from deterministic to statistical to allow for inter-annual variation in weather conditions.[30] In 1979, after President Carter's Regulatory Analysis Review Group (operating primarily out of the Office of Management and Budget), the White House Office of Science and Technology Policy, the Council of Economic Advisors, and API critically evaluated EPA's proposal, the agency set both the primary and secondary standards for ozone at 0.12 ppm. Subsequently, API, the Natural Resources Defense Council and several other groups petitioned the courts to review the standard. The DC Circuit Court of Appeals held in favor of EPA in its 1981 *API v. Costle* ruling. At the center of the controversy were the roles of official and *ad hoc* scientific advisory groups and of the Executive Office of the President (EOP) in the agency's decisionmaking process and EPA's use of a controversial evaluation procedure.[31] An outgrowth of the controversial 1979 ozone revision was the institutional formalization of the NAAQS review process. (For more on the historical development of the NAAQS process, see Jasanoff 1990, Ch. 6).

By 1983, the EPA Office of Research and Development Environmental Criteria and Assessment Office (ORD/ECAO) had initiated a review of the ozone CD in response to the statutory requirement to review the NAAQS by 1985.[32] It was not until 1985, however, that the Clean Air Act Science Advisory Committee (CASAC) reviewed the first draft of the CD. After CASAC's initial review, ORD/ECAO began revisions, and the EPA Office of Air and Radiation Office of Air Quality Planning and Standards (OAR/OAQPS) began drafting an Ozone Staff Paper (SP, an analysis forming the basis of policy options and staff recommendations for NAAQS). The following year, CASAC reviewed the first draft of the SP and indicated its satisfaction with the second draft of the CD in a "closure letter" to the Administrator.

During its 1987 review of the second draft of the SP, however, CASAC argued that EPA should capture in its review of the ozone NAAQS new, emerging data on the health effects and agricultural crop damages from longer exposures (6-8 hours and seasonal exposures). In response, ORD/ECAO drafted a Supplement to the 1986 CD while OAR/OAQPS revised the SP again. CASAC reviewed the documents in 1988. Although the committee urged EPA to complete its review as rapidly as possible (it was now 5 years overdue), CASAC's 1989 closure letter to EPA Administrator William Reilly revealed an internal division. The committee indicated that the Supplement to the 1986

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[29] Of the major photochemical oxidants in ambient air, only ozone (O_3) occurs at sufficiently high concentrations to be a significant health concern. Other photochemical oxidants such as hydrogen peroxide (H_2O_2) and peroxyacetyl nitrate (PAN) only produce effects at higher concentrations than those found in most cities (Horvath and McKee 1994).

[30] A deterministic form defines areawide attainment of the standard as no more than x (e.g., 1) exceedances of the standard in any given year. A statistical form defines areawide attainment in terms of an expected number of exceedances over a period (e.g., an average of no more than 3 exceedances over 3 consecutive years).

[31] The assessment procedure involved an expert judgment elicitation process known as subjective probability encoding. See Marraro (1982) and Nazar (1994) for case studies of the 1979 revision.

[32] The 1977 CAA Amendments required EPA to revise or reauthorize all of the NAAQS by Dec. 31, 1980, and every five years thereafter.

CD and the SP "provide an adequate scientific basis for the EPA to *retain or revise*" the NAAQS for ozone (McKee 1994, emphasis added). CASAC Chairman Morton Lippman reported that the committee did reach consensus on the definition of adverse health effects and sensitive populations groups, but only half of the members of CASAC believed the current ozone standard was adequately protective of human health (Lippman 1989). In particular, according to an ORD official, "CASAC members had a split view on the multi-

While ECAO, OAQPS, and CASAC were busily reviewing ozone science, the Bush administration and the Democratic-controlled Congress were immersed in legislative negotiations to revise the Clean Air Act (CAA). For the first time since 1977, it appeared that the political planets were aligned to enable a reauthorization of the act. According to McKee (1994), "Following numerous discussions and briefings within EPA on the need for modified and possibly more stringent [ozone] standards, it was determined that any such changes might be disruptive of the ongoing Clean Air Act negotiations and that such action should be delayed." According to an environmental lawyer, there was a meeting late in 1989 during which senior EPA officials made the political decision not to revise the NAAQS for ozone "unless they were forced to." Fearing that it would alienate stakeholders involved in the legislative negotiations, however, the agency was unwilling to announce its decision not to act. According to an OAQPS official, "There was a policy decision that the time was not ripe to take either action," i.e., go public with a decision that revisions are not appropriate or revise the standard on the basis of the existing record of decision. "The agency," said this source, "didn't want to rock the apple cart."

After the 1990 Clean Air Act amendments were enacted, however, the American Lung Association (ALA) and other plaintiffs filed suit in October 1991 to force EPA to complete its review of the NAAQS for ozone. The US District Court for the Eastern District of New York ordered EPA to announce its proposed decision on whether to revise the NAAQS for ozone by August 1992 and to announce its final decision by March 1993 (McKee 1994). In August 1992, then-Administrator William Reilly proposed that revisions to the ozone standards were not appropriate at that time. The notice did not take into account more recent studies that had not been assessed in the 1986 Criteria Document or its Supplement or reviewed by CASAC. EPA estimated that 2-3 years would be needed to assess and review the new information.

After the defeat of George Bush in the election of November 1992, President Clinton appointed Carol Browner as Administrator of EPA. In compliance with the court order, Administrator Browner finalized the decision not to revise the ozone NAAQS in March 1993. Table B-1 provides a summarized background of the 1993 decision not to revise the NAAQS for ozone. Shortly after President Clinton was re-elected in the November 1996 elections, EPA proposed to revise the NAAQS for ozone.

Table B-1. Background on the 1993 Ozone NAAQS Decision

1971	EPA sets NAAQS for photochemical oxidants at 0.08 ppm not to be exceeded more than 1 hour per year.
1977	EPA initiates review of Air Quality Criteria Document for Photochemical Oxidants
1978	EPA publishes final Criteria Document for Ozone and other Photochemical Oxidants. EPA proposes to raise the primary NAAQS to 0.10 ppm, retain the 0.08 secondary standard, base the photochemical standard on ozone, and change to standards with a statistical form (i.e., expected exceedances).
1979	After public comment and EOP review, EPA revises the NAAQS to 0.12 ppm (primary and secondary).
1981	U.S.D.C., DC upholds EPA's decision in *API v. Costle*.
1982	EPA/ORD/ECAO initiates review of the Ozone Criteria Document.
1985	CASAC reviews draft Criteria Document. EPA/ORD/ECAO prepares a new draft. EPA/OAR/OAQPS begins drafting Ozone Staff Paper.
1986	CASAC reviews 1st draft of Staff Paper, 2nd draft of Criteria Document, sends EPA Administrator closure letter indicating satisfaction with final Criteria Document.
1987	CASAC reviews 2nd draft of Staff Paper. CASAC recommends incorporating new scientific information.
1988	CASAC reviews draft supplement to the 1986 Criteria Document, 3rd draft of Staff Paper.
1989	CASAC sends EPA Administrator closure letter indicating that the Supplement and Staff Paper "provide an adequate scientific basis for the EPA to retain or revise" the NAAQS for ozone and suggests that EPA complete its review as rapidly as possible. EPA delays changing the standard to avoid disrupting ongoing Clean Air Act negotiations.
1990	Clean Air Act Amendments passed.
1991	American Lung Association sues to compel EPA to complete the ozone NAAQS review.
1992	Under court order, EPA Administrator Reilly proposes not to revise the NAAQS for ozone. EPA/ORD/ECAO initiates update of the CD.
1993	Administrator Browner announces that EPA would not modify the NAAQS for ozone.

2. Scientific Issues

Ozone is a highly reactive gas composed of three atoms of oxygen (O_3). In the upper atmosphere (the stratosphere), ozone filters out hazardous ultraviolet radiation from the sun. Stratospheric ozone is being depleted by chlorofluorocarbons (CFCs) and other chemical compounds. Closer to home in the troposphere, ozone is an atmospheric pollutant and the most important of a class of pollutants called photochemical oxidants. Ozone is described as a "secondary" air pollutant, because it is not emitted directly. Instead, it is formed by atmospheric chemical reactions involving nitrogen oxides (NO_x), volatile organic compounds (VOCs), and oxygen (O_2) in the presence of sunlight. High ambient levels of ozone generally occur only when temperatures exceed 80 to 90° F.

Four out of five interviewees responded that the scientific information available in 1993 was adequate for regulatory decisionmaking. (However, much of the information had not been through the formal NAAQS review process.) There is very little--if any--disagreement among respondents concerning whether the principal scientific studies demonstrate biological effects in humans, animals, and plants from ozone at levels below

the current standard of 0.12 ppm for exposure periods exceeding one hour. It is generally agreed that the effects of long-term exposure to low concentrations of ozone can produce greater effects than short-term exposure at peak concentrations, and that the effects become progressively more significant as the duration of exposure increases. "That the observations exist is incontrovertible," notes an industry scientist. "There is," however, "a raging debate about what is harmful and what is not." The question hinges on what constitutes an adverse effect in a continuum of measurable biological changes occurring down to background levels of ozone.

Health Effects

Respiratory effects have been the primary focus of study and concern for health effects of ozone. These include decreased lung function; respiratory symptoms such as coughing and shortness of breath; decreased exercise performance; increased airway sensitivity to allergens (e.g., contributing to asthma attacks); aggravation of existing respiratory diseases such as chronic bronchitis and emphysema; pulmonary inflammation and morphological effects (i.e., structural changes) in the lungs; and decreased ability to defend against respiratory infections. Ozone also causes a variety of detectable biological changes outside the respiratory system (e.g., in red blood cell morphology and enzyme activity) and appears to be one of many contributing factors to overall morbidity and mortality (Horvath and McKee 1994). [33]

Evidence of these effects comes from both human and animal studies. The best documented evidence of health effects of ozone exposure are temporary decreases in lung function (e.g., reduced lung capacity for a period of days).[34] Evidence of decreased lung function comes from controlled human exposure, field, epidemiology, and animal toxicology studies.[35] Clinical studies of human subjects under controlled exposure conditions (i.e., in exposure chambers) provide the most reliable quantitative human exposure-response data (in the 0.12 - 0.24 ppm range), but are limited to short-term (1-8 hr.) exposures and, generally, to healthy subjects.[36] According to an industry scientist, the "seminal" clinical ozone studies originated from the EPA Human Studies Division of the National Health and Environmental Effects Research Laboratory (NHEERL).[37] Heavily

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[33] At the time of the 1993 decision, relatively few studies of the effects of ozone on mortality had been conducted. However, a recent draft study reported by the independent Health Effects Institute indicates that ozone has an effect on mortality which is independent of the effects of ambient particulates, sulfur oxides, nitrogen oxides, and carbon monoxide. As a group, the other pollutants also appear to contribute to mortality, but their independent, individual effects could not be identified (*Risk Policy Report*, 4/19/96, p. 9).

[34] Clinical, field, and epidemiological studies have also reported associations between ozone levels as low as 0.10-0.12 ppm and a variety of mild-to-moderate respiratory symptoms (e.g., throat irritation and coughing), but these data are regarded as less reliable than the lung function measurements because the symptoms are inherently more subjective (Horvath and McKee 1994).

[35] Field studies contain elements of both controlled human exposures and epidemiological studies.

[36] In some cases, asthmatic subjects have been tested.

[37] NHEERL is a division of the Office of Research and Development (ORD). The EPA facility is located at University of North Carolina, Chapel Hill. There are a limited number of facilities capable of conducting clinical ozone exposure studies. According to an ORD official, other such facilities are located

exercising, healthy, young (mostly male) subjects have experienced measurable (i.e., small, but statistically significant) decreases in lung function during controlled exposures of ≥ 0.12 ppm ozone for 1-2 hours.[38] Measurable decreases in lung function have also been observed in intermittently exercising subjects exposed to concentrations as low as 0.08 ppm when exposures last 6-8 hours. The level of exercise and individual responsiveness (i.e., sensitivity) to ozone play a large role in the extent of lung function decrease at a given ozone concentration and exposure duration (Horvath and McKee 1994).[39]

Studies have also observed variability among individuals in their ability tolerate ozone. That is, after successive ozone exposures, the pulmonary function response attenuates to some degree. According to an EPA research official, this has described as a positive response (evidence that the effects are not long-lasting) or a negative response (indicating that the lungs' defenses are being circumvented). An industry scientist says, "with ozone tolerance, we don't know what's going on."

Epidemiology and field studies provide evidence of measurable decreases in lung function from ambient ozone exposures ranging from 0.08 to 0.12 ppm, depending upon length of exposure. However, it may be difficult to separate the independent effects of ozone from those of other air pollutants (e.g., particulates and acid aerosols) and other environmental variables (e.g., high temperature and humidity) in these studies. The observed effects may be an additive combination of factors, or alternatively, ozone may interact with these variables to produce decreases in lung function "greater than the sum

The first of several epidemiological studies of children engaged in normal activity at summer camps in the Northeast and California appeared in 1983 (Lippman *et al*. 1983).[40] These studies reported an association between decreased lung function in children and short-term exposure to ambient ozone concentrations. One of the summer camp studies (Spektor, Lippman, and Lioy 1988) reported measurable decreases in lung

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at the University of California, Santa Barbara; Rancho Los Amigos Medical Center, Downey, CA; and University of Michigan, Ann Arbor. According to this source, the U of C facility receives federal research support from the National Institute of Environmental Health Sciences (NIEHS) and EPA. Rancho Los Amigos is supported by the Electric Power Research Institute (EPRI), General Motors (GM), and other industry sources. The U of M facility is supported by GM.

[38] Average lung function decreases by approximately 5% for very heavily exercising human subjects exposed to 0.2 ppm ozone for 2 hours. However, there is considerable inter-individual variability in response. Controlled exposures to 0.12 ppm ozone during very heavy exercise have resulted in individual lung function decreases up to 16% for adults and up to 22% for children (Horvath and McKee 1994).

[39] Controlled studies of resting human subjects (conducted mainly in the 1970s) found little or no change in lung function. An increased level of exercise is associated with increased respiration rates, deeper breathing, and oral breathing. For a given ambient ozone concentration, the respiratory system receives an increased ozone dosage with elevated respiration rates. Oral breathing also results in greater penetration of ozone into the respiratory system.

[40] New York University Medical Center's Lippman and colleagues conducted studies in New York, New Jersey, and Connecticut with support from NIEHS and EPA. U of M, Ann Arbor's Higgins and colleagues conducted another youth summer camp study in the San Bernandino mountains of Southern California.

function in children exposed to ozone levels that did not exceed the current one-hour standard of 0.12 ppm. In some cases, the lung function decreases persisted for up to a week (Horvath and McKee 1994). An industry scientist finds the epidemiological studies with children in summer camps to be the most reliable data on ozone health effects because children at play during the summer are a highly exposed, susceptible population and because their level of activity was not under artificial experimental control. The first of a series of epidemiological studies of healthy adults engaged in outdoor exercise appeared in 1988 (Spektor, Lippman *et al*. 1988b). These studies also reported measurable decreases in lung function following short-term exposure at ozone concentrations below 0.12 ppm.[41] Thus, a variety of sources indicate measurable lung function decrements in different populations engaged in varying levels of activity in response to ozone concentrations at or below the current standard. However, these results beg the question of the health significance of measurable decreases in pulmonary function.

The summer camp studies also provided indications of persistent pulmonary inflammation and lung morphological changes in the children. According to Horvath and McKee (1994), these effects represent a potentially more important ozone health response than the more transient effects reported in most controlled exposure studies. Some have suggested that the responses could contribute to maldevelopment of the lungs in children. A number of studies provide evidence that short-term exposures to relatively low levels of ozone can inflame lung tissue. Researchers in EPA's Human Studies Division have reported pulmonary tissue inflammation in intermittently exercising subjects following exposure to 0.08 - 0.10 ppm ozone for more than 6 hours (e.g., Koren *et al*. 1991). While a limited number of such exposures would not cause permanent damage in most individuals because of the body's self-repair capacity, many long-term (e.g., months or years) animal studies have shown that repeated ozone exposures causing lung inflammation eventually result in morphological changes in the lungs and accelerated permanent loss of lung function (i.e., "lung aging"). An autopsy study of cadavers in Los Angeles County (where ozone levels are typically the highest in the country) also revealed a higher-than-expected number of lung lesions, although researchers were unable to determine the contribution from smoking (Horvath and McKee 1994).

An OAQPS official states that former CASAC panel chair Roger McClellan of the Chemical Industry Institute of Toxicology disputes the significance of lesions observed in the lungs of animals and of cadavers from Los Angeles associated with chronic exposures to ambient ozone levels. The reasoning is that lungs have excess capacity or a reserve capability and that the lesions are not manifest clinical symptoms. According to this official, the lung lesions might impinge on quality of life by causing shortness of breath from mild exertion with age rather than causing or contributing to mortality, as some have suggested. According to an industry scientist, there is considerable uncertainty about the reversibility of the pulmonary lesions observed in the long-term animal studies. "The

[41] In addition to the studies by Spektor and colleagues, a group from the Harvard School of Public Health also conducted a study of adult hikers on Mt.Washington, NH that found an association between ambient ozone levels and decreased lung function (Korrick *et al*. 1992).

problem is to determine what is a homeostatic response, a normal reversible change associated with defense, as opposed to what changes are associated with permanent, long-term damage." An ORD official also points to the uncertainties in extrapolating the results of the chronic exposures from animals to humans. "We have made some progress on dosimetric models for extrapolating from animals to humans. The hope was that they would be ready for this round of review, but we're not there yet."

Non-Health Effects

The effects of ozone exposure on vegetation have been the primary focus of the secondary standard. There is general acknowledgment that vegetative effects occur at levels of exposure below 0.12 ppm and that certain plant species are more sensitive to ozone than are humans. According to an OAQPS official, "it is certain that ecological effects are occurring." Similar to the situation of ozone health effects, however, there is no collective certainty about what to make of the observed changes. Many early "phytotoxicity" studies assessed the effects of ozone on plants in terms of foliar injury (e.g., leaf necrosis--dead leaves--or leaf drop); however the extent of foliar injury (in terms of percent of the crop exhibiting symptoms) can be much greater than that of crop yield loss. Conversely, significant yield losses can occur with little or no foliar injury (Tingey *et al*. 1994). An ORD scientist hypothesizes that tropospheric ozone may have its greatest ecological impact not on plant productivity but by exerting selection pressure that ultimately alters species composition within ecological communities and genetic variability within species. For example, the fact that many trees in the eastern US are less sensitive to ozone than their western cousins may be an adaptive evolutionary response to higher ozone levels. Whether such changes are to be regarded as "important" is another issue.

The chief concern for the secondary effects of ozone has been on agricultural and timber crop yields due to their economic value. Using data collected by a multi-site experimental program initiated in 1980 (the National Crop Loss Assessment Network, NCLAN), EPA analysts estimate that current ambient ozone exposures result in a 14% yield loss for major US crops and that yield losses would continue to occur even if all US sites would attain the current secondary NAAQS of 0.12 ppm (Tingey *et al*. 1994). However, reviewers (e.g., Adams *et al*. 1984) have criticized NCLAN's experimental design, use of sensitive crop cultivars which maximize plant response to ozone, and failure to incorporate agricultural practices (e.g., increased fertilization) that could offset the yield reductions caused by ozone exposure.[42] A factor that has seriously impeded the assessment of the effects ozone on crops and natural resources is the lack of rural ambient air monitoring sites.

[42] The primary criticism of the experimental design has to do with the narrow set of ozone concentrations that were used. A large number of experimental replications over a few concentration levels increases the chances that the study would detect effects even if they are relatively small and may facilitate a mechanistic understanding of the effect of ozone on plant growth. However, Adams *et al*. (1984) observe that spreading the experimental trials over a larger number of concentration levels provides better input into an exposure-response analysis.

The selection of the ozone exposure indicator related to plant yields has been a difficult problem in formulating a secondary standard. The indices which best predict yields are measures of cumulative exposure that give greater weight to peak exposure days (e.g., a weighted sum over the growing season). There remain questions, however, regarding the practicality of this form of the indicator for regulatory purposes (Tingey *et al*. 1994).

The Effects of Weather

Hot, stagnant weather increases ambient ozone levels. Ozone and its precursors (VOCs and NO_x) are also transported considerable distances by air masses. As a result, ozone levels--and the number of exceedances of the NAAQS level--are sensitive to variations in meteorological conditions (Yosie *et al*. 1994). In addition, high heat and humidity appear to intensify the health effects of ozone (Horvath and McKee 1994).

3. The Process within EPA

Setting the Agenda

The 1991 ALA lawsuit against EPA was the factor most frequently cited by respondents as being responsible for getting the ozone NAAQS on the agency's agenda. According to an independent policy analyst, "They [EPA] were going to delay as long as they could until ALA forced the issue." Of course, legislative provisions requiring periodic review of the NAAQS and permitting citizen lawsuits enabled ALA's agenda-setting action.

According to an air program official, something that contributed to elevating ozone on the agency's agenda was that prior to the 1989 decision not to revise the standard, "Vocal scientists, particularly [former Assistant Administrator for ORD] Bernard Goldstein and [CASAC Chairman] Mort Lippman, met with the Administrator and pounded the table that they had studies that ... suggested that [adverse health effects] were happening on a longer time frame, 6-8 hours," than the form of the current standard (1 hour).

Another factor that may have contributed indirectly to forcing ozone up the EPA agenda was the scientific information that agency researchers had generated since the 1988 Supplement to the Criteria Document. This data demonstrated that one could induce measurable biological changes in humans, animals, and plants at ever-lower ozone concentrations. From 1988-1992, clinical studies reported by EPA's Human Studies Division incrementally lowered the bar by increasing the subjects' level of activity and duration of exposure. Similarly, NCLAN researchers designed experiments to detect plant responses at the lowest levels of ozone. In both cases, the pattern of searching for the lowest levels of ozone at which biological effects could be detected was consistent with the misguided presumption under the Clean Air Act of a threshold concentration below which no adverse effects would occur. According to an ORD scientist, the EPA air

program framed the research question as "at what level can you detect a change." This source describes the situation as one in which "analysts, not policymakers, were involved in discussing what effects to measure." Absent these and other studies documenting measurable responses to ozone concentrations below the existing standard, ALA presumably would have had little institutional incentive to compel the agency to complete its review.

Assessing the State of the Science

According to an environmental lawyer, the most important studies on the effects of 6-8 hr. low-level ozone exposures were reported in 1989-93, after the Supplement to the 1986 Criteria Document was closed. An ORD official says the agency was overwhelmed attempting to keep up with the science. "There had been over 1,000 new scientific papers in the literature since the last ozone decision, and the agency is expected to analyze each one." No formal NAAQS review of the science was conducted prior to the 1993 decision not to revise the ozone standard, but EPA staff scientists who tracked the expanding literature believed that the information that had accumulated since the 1988 CD Supplement "pointed in the direction of multi-hour exposures having effects on pulmonary responses at lower concentrations than the current standard," according to another ORD official.

Communicating the Science to Agency Leadership

Sometime during the winter of 1992-93, between unpacking boxes and "Reinventing EPA," members of the EPA transition team and the new administration were briefed on the ozone NAAQS by OAQPS staff. The staff indicated the "direction" in which the new science was pointing, according to an EPA official. But since ECAO was in the earliest stages of preparing a new Criteria Document at the time of the briefing,[43] it was clear that there would be insufficient time to conduct a full-blown NAAQS review prior to the court-ordered deadline. According to a former EPA air program official, this sort of communication, in which decisionmakers are briefed about the "directionality" of the evolving science and the studies currently underway that could have a major impact on the rulemaking is typical of a decision not to revise a standard.

The Role of External Scientists in the Process

Although external scientists apparently had no direct involvement in EPA's 1993 decision not to revise the NAAQS for ozone, CASAC's historical involvement played a significant role. In contrast to the position of the official scientific advisory panel which reviewed EPA's 1979 revision, CASAC adopted a more precautionary approach regarding what constitutes an adverse health effect in the 1980s review of the Criteria Document for ozone (Jasanoff 1990, pp. 115-116). By defining reversible changes in lung function and non-clinical symptoms as adverse health effects, CASAC set a precedent that narrowed

[43] In 1992, ECAO released a Draft Supplement to the Air Quality Criteria for Ozone summarizing selected new information on the effects of ozone on health and vegetation (Horvath and McKee 1994).

policy options and paved the way for the lack of consensus on a policy recommendation. After setting this precedent, according to an independent policy analyst, the committee was "unwilling to redefine reversible health effects resulting from short-term exposures as 'not adverse.'" While the committee justified their negotiated definition of reversible changes as adverse on the basis of the understood effects of short-term studies, the concern of some members may have been focused more on the poorly understood effects of chronic exposures. As this source suggests, "In part, this [the committee's precautionary definition of adverse effects] may be due to a recognition by the committee of the inability of the available observational methods to capture potentially irreversible effects resulting from chronic exposures."

Respondents stated that the significance of the reported effects from exposures below 0.12 ppm for periods of 6-8 hours was the primary source of division within CASAC that lead it to recommend that EPA "*retain or revise*" the existing NAAQS for ozone. These were the same effects that the committee had, by "consensus" defined as adverse. Apparently, this consensus was a fragile one. According to EPA officials, there was a strong consensus within CASAC that the standard should not be relaxed, but some committee members felt that the level of the 1-hour standard should be lowered or the form of the standard should be changed to an 8-hour average, while others believed that the database was not sufficiently "ripe" to recommend any change. According to an industry scientist, Morton Lippman, CASAC chair during the 1980s review, "firmly believes that his studies in the children's camps demonstrate detrimental effects at ambient

4. Science in the Final Decision

According to a former senior EPA official, the Reilly administration proposed not to revise the ozone NAAQS in 1992 "because CASAC was divided and the 1990 CAA amendments had recently been passed." Regarding the role of science in the decision not to revise, an OAQPS official says, "Based on record up through 1988, there was not a compelling case to revise the standard. And if there was a compelling case, it would have never gotten through the agency."

The Reilly administration proposed not to revise the ozone NAAQS in 1992 "because CASAC was divided and the 1990 CAA amendments had recently been passed."

There was apparently some informal calculus which considered the science in terms of the incremental benefits arising from a marked change in the form, if not in the overall stringency, of the standard. (Recall that such a change was enacted in the 1987 PM-10 revision. See accompanying case study on particulate matter.) An EPA air program official noted the resultant "disruption that would occur in the ozone control program." Changing the form of the standard from 1-hour to 8-hours would require "new models, new monitoring procedures, and would essentially bring the control program to a stop for 2-3 years." This raised the question in the minds of air program officials of whether the incremental protection that the agency would gain by simply adopting a

longer averaging time was worth the disruption in the program. "We concluded that it was not ready. It was more strategic than tactical," says this source.

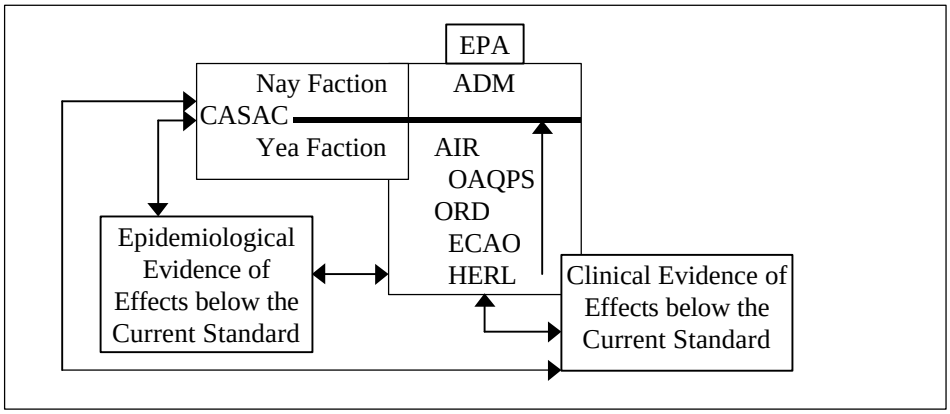
The 1993 decision not to revise the ozone NAAQS was "science-driven" in that EPA needed sufficient time to adequately analyze the vast amount of new information that had accumulated on ozone since 1988.

According to respondents, the focus of decisionmaking by the Browner administration early in 1993 was on negotiating the ozone NAAQS review schedule with the plaintiff (ALA). Although the role of science in the final decisionmaking was not substantive, the scientific review *process* was considered. In the view of an ORD official, the 1993 decision was "science-driven" in that EPA needed sufficient time to adequately analyze the vast amount of new information that had accumulated on ozone since 1988. Of course, the Browner administration had no control over the early stage at which it inherited the ozone NAAQS review process from the Reilly administration. Furthermore, despite the members' familiarity with the available scientific literature, the lack of consensus within CASAC ruled out the possibility that the committee's review would be rapid or perfunctory. An OAQPS official sympathizes with the Administrator's position in finalizing the agency's decision not to revise the standard. "In fairness to Browner, she had no choice but to sign it."

5. Concluding Observations

In terms of a fate and transport analogy, this case illustrates that for criteria air pollutants, a full-blown NAAQS review is required to make science "available for uptake" by EPA decisionmakers. Information generated inside and outside EPA may be released into the public domain for several years and subjected to peer-review. It may permeate throughout the agency, with its implications fully understood by staff. But the information is not actionable until the NAAQS procedural requirements are satisfied. Furthermore, the lack of a consensus recommendation from CASAC to revise the standard provides the Administrator with "an out" to justify not revising the NAAQS on the basis of "scientific uncertainty." Therefore, the scientific evidence of effects at levels below the existing standard which is available to the decisionmaker can be neutralized by policy disagreements within CASAC. This is illustrated schematically in Figure B-1.

Figure B-1. Fate and Transport Dynamics for Science in the 1993 Decision Not to Revise the Ozone Standard.



Epilogue: After EPA's 1993 decision not to revise the NAAQS for ozone, the American Lung Association sought judicial review of the EPA decision, citing the agency's failure to consider all relevant, available scientific information. The decision was voluntarily remanded to the agency, but in 1994, the ALA again sued (unsuccessfully) to force EPA to complete the review by the end of 1995 (*Environment Reporter*, 10/14/94). In 1995 (10 years after the statutory deadline for completing the review), OAQPS released a staff paper which recommended changing the standard to 0.07 ppm to 0.09 ppm measured over eight hours. Noting the continuum of biological effects observed down to background ozone levels, CASAC endorsed replacing the 1-hour primary standard with an 8-hour standard but did not recommend any specific level. In CASAC's 1995 closure letter to Administrator Browner, the committee stated that "ozone may elicit a continuum of biological responses down to background concentrations. This means that the paradigm of selecting a standard at the lowest-observable-effects level and then providing an 'adequate margin of safety' is no longer possible" (*Environment Reporter*, 1/19/96, pp. 1756-1757).

Shortly after the elections in November 1996, EPA proposed to revise the NAAQS for ozone, basing the primary standard on 8-hour averages, and setting it at a level of 0.07 - 0.09 ppm. The agency also proposed to replace the current secondary standard with one of two alternative standards: one identical to the new primary standard or, alternatively, a new seasonal standard expressed as a sum of hourly ozone concentrations greater than or equal to 0.06 ppm, cumulated over 12 hours per day during the ozone season (*Fed. Reg.*, Vol. 27, p. 1672).

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LIST OF ABBREVIATIONS

ALA	American Lung Association
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CD	Criteria Document
ECAO	Environmental Criteria and Assessment Office
EPA	Environmental Protection Agency
NAAQS	National Ambient Air Quality Standard
NCLAN	National Crop Loss Assessment Network
NIEHS	National Institute of Environmental Health Sciences
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
ORD	Office of Research and Development
SP	Staff Paper