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Air Quality Standards: The Decisionmaking Process

John E. Blodgett and Larry B. Parker, Resources, Science and Industry Division

Updated April 9, 2002

Abstract. The decisions by the Administrator of the Environmental Protection Agency (EPA) in 1997 to revise the National Ambient Air Quality Standards for ozone and particulate matter refocused attention on the criteria and the process by which these decisions are made. Tracing the steps of the decision process, this report identifies the statutory criteria established by the Congress and summarizes the administrative procedures the Agency follows in setting these standards—and in reviewing them every five years.

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Air Quality Standards: The Decisionmaking Process

Updated April 9, 2002

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Air Quality Standards: The Decisionmaking Process

Summary

The decisions by the Administrator of the Environmental Protection Agency (EPA) in July 1997 to revise ambient air quality standards (NAAQS) for ozone and particulate matter refocused attention on the criteria and the process by which these decisions are made. The new standards were the subject of numerous oversight hearings as well as litigation, which culminated in a Supreme Court ruling February 27, 2001. The court upheld the NAAQS-setting procedures at question, in particular definitively rejecting the consideration of costs in setting NAAQS.

However, the court's ruling also raised questions concerning the implementation of the EPA's new ozone standard. With continuing controversy over the PM and ozone standards, along with other concerns about the Clean Air Act (CAA), the expiration in 1998 of the authorizations for appropriations in the statute, and the Bush Administration's proposal for amendments, it is possible that the Congress may take up amendments to the CAA. If so, the NAAQS decisionmaking process may command attention, especially with respect to how scientific evidence is used. Because of the role NAAQS might play in bringing amendments onto the legislative agenda, this report provides background on the processes and procedures for setting and revising NAAQS. The basic steps are as follows:

- ! EPA identifies a pollutant that is emitted from numerous or diverse mobile or stationary sources and that endangers public health or welfare.
- ! EPA prepares a "criteria document" that summarizes the scientific information relevant to the pollutant; this document is formally reviewed by a Clean Air Scientific Advisory Committee (CASAC).
- ! EPA prepares a "staff paper" that summarizes the criteria document and lays out policy options for the Administrator; it is also reviewed by CASAC.
- ! Based on the criteria document, the staff paper, and CASAC's "closure letters," the Administrator proposes a NAAQS; this proposal is published in the Federal Register, a "docket" created, and an opportunity for public review and comment provided. And,
- ! The Administrator's final decision, "which, in the judgment of the Administrator, ... [is] requisite to protect the public health ... or public welfare."

The CAA spells out requirements for the criteria document, the CASAC review, the basis on which the Administrator chooses the standard, and the procedural process for promulgating the standard. EPA administratively added the preparation of a "staff paper"; in addition, Executive Order 12866 requires a Regulatory Impact Analysis (RIA), although the economic analysis is essentially irrelevant to the decision a NAAQS. Other laws also raise regulatory assessment issues. The Act requires EPA to revisit each NAAQS every 5 years, following the same process.

Several aspects in the NAAQS-setting process have been the foci of attention in the past and might be revisited: these include the Act's requirement that NAAQS be set to protect health with an adequate margin of safety, without consideration of costs; the process for verifying the scientific underpinnings of a proposed standard; the boundaries on the Administrator's judgment in accounting for risk and uncertainty in setting NAAQS; EPA's responsiveness to public comments; and the

extent to which EPA must respond to requirements exogenous to the CAA that direct EPA to consider impacts of its regulations.

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Air Quality Standards: The Decisionmaking Process

Introduction

Decisions in July 1997 by the Administrator of the Environmental Protection Agency (EPA) to revise the national ambient air quality standards (NAAQS) for ozone and particulate matter (PM) refocused attention on the criteria and the process by which these decisions are made. The new standards have been attacked both as overly stringent and as inadequately protective of health; as ignoring costs and as giving costs too much deference; as going beyond what is scientifically conclusive; and as failing to be sufficiently precautionary.¹ These issues were the subject of numerous oversight hearings as well as litigation, which culminated in a Supreme Court ruling February 27, 2001. The court upheld those NAAQS setting procedures at question, in particular definitively rejecting the consideration of costs in setting NAAQS.

However, the court's ruling also raised questions concerning the implementation of the EPA's new ozone standard. With the court's decision, continuing controversy over the PM and ozone standards, along with other concerns about the Clean Air Act (CAA), the expiration in 1998 of the authorizations for appropriations in the statute, and the Bush Administration's air quality initiative that would amend the Act,² it is possible that the Congress may take up amendments to the CAA. If so, the NAAQS decisionmaking process may command attention, especially with respect to how scientific evidence is used – and possibly reopening the question of whether costs should be considered in setting NAAQS.

Because of discrepancies in views on what transpired — or should have transpired — in EPA's development of the 1997 ozone and PM standards, this report provides background on the processes and procedures for setting and revising NAAQS. It lays out the steps of the decision process and identifies the statutory criteria established by the Act for NAAQS, to aid the reader's understanding of the Act's policy for NAAQS. It does not evaluate the decisionmaking process nor assess EPA's decisions on the ozone and PM NAAQS; nor does it address the several other categories of pollutants (e.g., hazardous air pollutants) or other standards-setting activities under the Act.

¹See CRS Report 97-8, *Air Quality: EPA's New Ozone and Particulate Matter Standards*.

²George W. Bush, The White House, "The Clear Skies Initiative," Feb. 14, 2002. For current information on clean air legislation, see James McCarthy, *Clean Air Act Issues in the 107th Congress*, CRS Issue Brief IB10065.

Background

The process by which EPA sets and revises NAAQS evolved over many years. Initially, federal air quality law focused on supporting state programs, through the conduct of research (a central, federal research program was more efficient than 50 state research efforts) and through technical and financial support (regulation was seen as a state and local matter). By the late 1960s, the federal research effort, located in the National Center for Air Pollution Control, Public Health Service, Department of Health, Education, and Welfare (HEW), included the preparation of “criteria” — a summary of scientific knowledge concerning selected air pollutants — and “guidelines” — a summary of control technologies. These criteria and guidelines were to support state programs to control air pollution.

As environmental awareness heightened in the late 1960s, the federal role enlarged. With the Clean Air Act Amendments of 1970, the federal clean air program was moved to the newly created EPA³ and reconstituted, with the federal government becoming responsible for establishing “national ambient air quality standards” for air pollutants endangering public health or welfare and resulting from numerous or diverse mobile or stationary sources. The states remained primarily responsible for developing implementation plans to attain and maintain compliance with those national standards. Major amendments in 1977 and 1990 refined the NAAQS setting and implementation process. The 1977 amendments formally established the Clean Air Scientific Advisory Committee (CASAC) and the 5-year review process. The 1990 amendments increased federal guidance to states in implementing existing NAAQS.

Thus the present process for setting and revising NAAQS consists of the statutory steps incorporated in the CAA over a series of amendments. In addition, several other steps of varying degrees of import have been added by the EPA, by executive orders, and by subsequent regulatory reform enactments by the Congress. The steps are depicted in appendix I; for an example chronology of the steps, see appendix II. The documentary language spelling out those steps, along with explanatory notes, follows.

NOTE: CAA language is in **bold**; legislative history language, i.e., from reports on amendments to the CAA, is in ***bold italics***; language from statutes other than the CAA is in *italics*.

Citations to ozone or PM standards setting refer to the documentation for the 1997 ozone and PM NAAQS.

³EPA was created by Reorganization Plan No. 3 in 1970, reprinted as 42 U.S.C. §4321 note; the Agency went into operation December 2 of that year.

Criteria Air Pollutants

The pollutants for which NAAQS are set are often called “criteria pollutants.” This term reflects the evolution of the process. Before there were NAAQS, the Air Quality Act of 1967 (a predecessor of the CAA) required the Federal government to list air pollutants and to prepare “criteria” — a report summarizing scientific evidence concerning their health effects. The states then set standards. Thus the air pollutants for which NAAQS were later set were originally air pollutants for which the Office of Air Quality in HEW prepared “criteria.” The current language specifying the listing of “criteria” air pollutants, as modified by the 1970 and 1977 amendments to the CAA, is as follows:

The Administrator shall ... publish, and shall from time to time thereafter revise, a list which includes each air pollutant — (A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare; [and] (B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources ...
[CAA §108(a)(1)]

With the Clean Air Act Amendments of 1970, the EPA became responsible for determining national ambient air quality standards for the “criteria pollutants” — those of such national scope in release or effect that national standards are appropriate. Also, EPA was to assist states in attaining these standards through grants and technical assistance,⁴ and could impose sanctions on states for failures to fulfill their obligations. At present, six pollutants are designated “criteria pollutants” for which NAAQS have been set: particulate matter⁵ (PM), ozone (O₃, a key measure of smog), nitrogen dioxide (NO₂, or, inclusively, nitrogen oxides,⁶ NO_x), sulfur oxides (SO_x, or, specifically, SO₂), carbon monoxide (CO), and lead (Pb).

⁴For example, in conjunction with setting NAAQS, the CAA requires EPA to prepare information on air pollution control technologies:

Simultaneously with the issuance of criteria ..., the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control technologies, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. [CAA, §108(b)(1)]

The preparation of these “guidance documents,” as they are known, is not reviewed in this report.

⁵The original PM NAAQS was for “Total Suspended Particulates”; the standard was later focused on particles smaller than 10 microns (PM₁₀) and in 1997 EPA proposed that a standard be added for particles smaller than 2.5 microns (PM_{2.5}).

⁶The NAAQS is for NO₂; nitrogen gases that are ozone precursors are referred to as NO_x.

National Ambient Air Quality Standards

The Administrator ... shall publish ... regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued [CAA §109(a)(1)(A)]

A NAAQS is a uniform, national standard establishing the maximum permissible concentration of an air pollutant in the ambient air — the “portion of the atmosphere, external to buildings, to which the general public has access.”⁷ The CAA directs the Administrator to set a NAAQS at a level that provides protection from adverse effects on the public health and welfare. The Act provides for “primary standards” to protect health with a margin of safety and for “secondary standards” to protect welfare.

Primary Standards

National primary ambient air quality standards ... shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. [CAA §109(b)(1)]

An ambient air quality standard ... should be the maximum permissible ambient air level of an air pollution agent or class of such agents (related to a period of time) which will protect the health of any group of the population. [Senate Report No. 91-1196, p. 10]

As stated in §109, a NAAQS defines the acceptable concentration of an air pollutant in the ambient air necessary to protect health. As discussed later, costs are not considered in setting primary standards. Areas — defined as air quality control regions — complying with the standard are designated “attainment areas” and areas in which the pollutant exceeds the standard are designated “nonattainment areas.” An area can be in attainment for one air pollutant and out of attainment for another.

Although a primary NAAQS has a federally enforceable deadline, a NAAQS does not itself establish what to do when concentrations exceed the standard (nor how to protect clean air in attainment areas). Other provisions of the CAA lay out the process of implementation (specifically, §110). For nonattainment areas, this includes monitoring ambient air quality to determine compliance; requiring states to prepare state implementation plans (SIPs) to bring areas not in compliance into compliance; and requiring states to implement their plans to achieve and maintain the NAAQS by a specified deadline (Title I, Part D of the Act). Federal measures to protect air quality include new source performance standards (§111), which are national standards on specified categories of new sources of selected air pollutants, and mobile source emission standards (§202). Also, the federal government continues to prepare “guidance documents” spelling out available control measures

⁷40 CFR §50.1(e). Air within workplaces is subject to regulation by the Occupational Health and Safety Administration.

for the NAAQS pollutants. Finally, in attainment areas where the air is cleaner than NAAQS, the CAA establishes a program for new source permitting to “maintain” that clean air quality (Title I, Part C).

“Margin of Safety”.

... [A]llowing an adequate margin of safety ... [CAA §109(b)(1)]

In setting such [national ambient air quality] standards the [Administrator] should consider and incorporate not only the results of research summarized in air quality criteria documents, but also the need for margins of safety. Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified. [Senate Committee on Public Works, Report No. 91-1196 (1970), pp. 9-10]

The phrase, “margin of safety,” has been central to several debates.

The phrase seems to imply that NAAQS are based on thresholds — that there is a concentration of a pollutant below which adverse health effects do not occur. In this view, the Administrator determines the “no effect” threshold for the pollutant from the scientific evidence in the “criteria document” and then adds a safety factor. From this perspective, the issue is how large the margin of safety should be. In a report on automobile emissions in 1974, a panel of the National Academy of Sciences observed that “the safety factors provided by the air standards are much smaller than is usual in regulating other environmental pollutants such as radioactivity...”⁸ This could be interpreted as suggesting the need for tighter standards,⁹ thus providing a larger margin of safety.

In fact, scientists find that there seem not to be clear thresholds for air pollutants. The 1974 National Academy of Sciences panel on auto emissions observed that—

... in no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at and above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, with no sharp lower limit.¹⁰

⁸National Academy of Sciences, *Air Quality and Automobile Emission Control*, Vol. 1 (September 1974), p. 6.

⁹U.S. Congress, House, Committee on Interstate and Foreign Commerce, *Clean Air Act Amendments of 1977*, House Rept. No. 95-294, to accompany H.R. 6161 (95th Congress, 1st session) (Washington, D.C.: U.S. Govt. Print. Off., 1977), p. 182.

¹⁰National Academy of Sciences, *Air Quality and Automobile Emission Control*, Vol. 1 (September 1974), p. 17.

The 1996 reviews of the ozone and PM standards likewise concluded that no threshold of adverse effects could be found for either pollutant.

The inability of scientists to find a threshold has led to contention in the setting of NAAQS. Some argue that if there is no threshold, then there cannot be a margin of safety and as a result the whole NAAQS process of necessity becomes a risk management decision — that is, one in which the Administrator balances risks with costs to decide where to set the standard. Others argue that the lack of a threshold justifies the tightest possible standards.

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

The legislative history of the CAA only briefly touches on the “margin of safety” phrase. The Senate Report 90-1196 (accompanying legislation that became the Clean Air Amendments of 1970), quoted at the beginning of this section, clearly indicates that the “margin of safety” is designed to protect against the potential for adverse effects to occur at pollutant concentrations below those known to cause harm. Thus, regardless of the existence of a threshold, the margin of safety is a factor the Administrator would consider in making choices involving uncertainties embedded in the definitions of which vulnerable population groups to protect and of what effects are adverse health effects: these issues are discussed later. Similarly, House Report 95-294 (accompanying legislation that became the Clean Air Act Amendments of 1977), after quoting the National Academy of Sciences about the “smaller than usual” safety factor in NAAQS and about the lack of evidence for thresholds, suggested “*greater not lesser control of emissions are likely to be needed.*”¹¹ The precautionary premise of the act seems manifest in the phrase “margin of safety” regardless of the existence of thresholds; and the inference that the phrase calls for consideration of costs has been consistently rejected.

Secondary Standards

Any national secondary ambient air quality standard ... shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with presence of such air pollutant in the ambient air. [CAA §109(b)(2)]

¹¹U.S. Congress, House, Committee on Interstate and Foreign Commerce, *Clean Air Act Amendments of 1977*, House Rept. No. 95-294, to accompany H.R. 6161 (95th Congress, 1st session) (Washington, D.C.: U.S. Govt. Print. Off., 1977), p. 182.

All language referring to effects on welfare includes, but is not limited to, effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants. [CAA §302(h)]

Secondary NAAQS define the concentration of an air pollutant in the ambient air necessary to protect the “public welfare.” Secondary standards are implemented in the same manner as primary NAAQS, with the key difference that there is no federally enforceable specified deadline for attainment. Most secondary NAAQS have been set at the same level as the primary NAAQS, but they can be set at levels more or less stringent if justified by available evidence.

Setting NAAQS

Setting and Reviewing NAAQS

The process for setting a NAAQS is a multistage one, and repeats regularly as the CAA requires each NAAQS to be reviewed every 5 years using the same process, to ensure that each NAAQS is based on the most recent scientific information. The CAA is quite specific on certain steps of the process: in particular, on the preparation of a “criteria document” summarizing the scientific information, on the review of that document by an independent scientific committee, on the criteria to be used by the Administrator in deciding on the final standard, and on the procedural process for promulgating the standard. In addition, EPA has administratively added a key step, the preparation of a “staff paper” that summarizes the criteria document and lays out policy options; and Executive Order 12866 requires a Regulatory Impact Analysis (RIA), although the economic analysis it contains is legally irrelevant to the actual decision on the standard. Finally, there are a number of regulatory assessment requirements in law that impinge on the process — but have limited substantive impact on the decision itself. These stages are discussed below (see also Appendix I).

Criteria Document.

The Administrator shall issue air quality criteria for [each] air pollutant ... included ... [on the] list [CAA §108(a)(2)]

The “criteria document” precedes the NAAQS both in its appearance in air pollution control law and in the process of setting NAAQS. In the early stages of the evolution of Federal air pollution control law, the Federal role focused primarily on research and on providing financial and technical advice to states. This role was exemplified in the requirement that the Public Health Service (which was responsible for Federal air pollution activities before EPA) prepare a “criteria document.”

“Air quality criteria [documents] are an expression of the scientific knowledge of the relationship between various concentrations of

pollutants in the air and their adverse effects on man, animals, vegetation, materials, visibility, and so on.

“Air quality criteria can and should be used in developing air quality standards. Criteria and standards are not synonymous. Air quality criteria are descriptive; that is, they describe the effects that can be expected to occur whenever and wherever the ambient air level of a pollutant reaches or exceeds a specific figure for a specific time period.”

[Dr. Middleton, Director, National Center for Air Pollution Control, Public Health Service, quoted in Senate Committee on Public Works Report 403 on the Air Quality Act of 1967, p. 26.]

Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. [CAA, §108(a)(2)]

In 1970, when the Clean Air Amendments of 1970 established the federal role in setting NAAQS, the “criteria document” became the basic technical underpinning of the standards-setting process. Explicitly, the preparation, review, and use of the “criteria document” was to be objective and scientifically validated. It is scientifically peer reviewed by an advisory committee — established by statute in the 1977 amendments — and by other federal departments and agencies. Much of the review process is open to the public, and the final criteria document is made public:

The issuance of air quality criteria ... shall be announced in the Federal Register and copies shall be made available to the general public. [CAA, §108(d)]

The criteria document is prepared in the Office of Research and Development by EPA scientists (with the advice of and review by a scientific advisory committee, described below). Reviewing the scientific literature for all studies relevant to the air pollutant, the preparers consolidate information pertinent to indicating the kinds and magnitudes of effects resulting from the pollutant’s presence in ambient air, assess the robustness of the studies, endeavor to resolve inconsistencies, and evaluate findings. Key components of the scientific evidence include epidemiological studies that examine the relationships between ambient pollutant levels and public health and welfare; clinical studies that examine human responses to controlled levels of pollutants, for example in air chambers; and animal studies. Typically, the studies included have undergone peer review and been published in the open literature, but on occasion some other studies, such as preliminary reports on ongoing research, may be included if they meet other standards of scientific reporting.

Criteria documents are major undertakings: the 1996 ozone criteria document contains over 1,500 pages and evaluates nearly 190 scientific studies; the 1996 PM criteria document contains 2,400 pages and evaluates some 80 studies. Each document took about one year to draft; review and revisions took another year to come to closure.

Staff Paper.

This [staff paper] assessment is intended to help bridge the gap between the scientific review contained in the [criteria document] and the judgments required of the Administrator in setting ambient standards for PM. Thus, emphasis is placed on identifying those conclusions and uncertainties in the available scientific literature that the staff believes should be considered in selecting particulate pollutant indicators, forms, averaging times, and levels for the primary (health) and secondary (welfare) standards. [EPA, *Particulate Matter Staff Paper* (1996), p. I-1]

Based on the criteria document, EPA scientists and policy experts prepare a staff paper. It is developed in the Office of Air Quality Planning and Standards of the Office of Air and Radiation. This document is not required by the CAA; it is an administrative step designed to facilitate the EPA Administrator's decision. It lays out options for a NAAQS standard — e.g., whether to set a standard, at what level(s) it might be set, and methods for measuring compliance — along with justifications from the criteria document. Like the criteria document, the staff paper is reviewed by the scientific advisory committee.

Clean Air Scientific Advisory Committee.

The Administrator shall appoint an independent [clean air] scientific review committee [CASAC] composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

... [T]he [clean air scientific advisory] committee ... shall ... review ... the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate

Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) 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. [CAA, §109(d)(2)]

The 1967 Air Quality Act required the Secretary of HEW to consult with “appropriate advisory committees” (along with Federal departments and agencies) when preparing criteria documents. The Secretary established a National Air Quality Criteria Advisory Committee, having a membership broadly representative of industry, universities, conservation interests, and all levels of government. This committee actively participated in the rewriting of the Sulfur Oxides Criteria

Document published in 1969, and in the preparation of subsequent criteria documents. This general requirement for consultation was replaced in 1977 by the specific requirements creating CASAC, with its responsibilities for reviewing the scientific basis of the Administrator's decisions on NAAQS. The legislative history concerning the CASAC provision emphasizes its independence:

This committee is intended to assist the Administrator, but it is also intended to have complete independence. This independence will help provide an outside mechanism for evaluating whether any pollutant may reasonably be anticipated to endanger public health or environment, for evaluating the scientific and medical data which bear on this question, and for reviewing gaps in the available data and recommending additional needs for research. [Committee on Interstate and Foreign Commerce, House Rept. No. 95-294 (1977), p. 182]

The seven-member CASAC creates a panel to review each NAAQS. This panel consists of the members of CASAC plus consultant members to assure full coverage of the expertises needed to assess fully the issues involved. For the ozone review, a panel of 15 was convened; for the PM review, the panel consisted of 21.

The panel members meet to review each criteria document and staff paper as it is prepared, recommend improvements, and after further meetings and reviews sign off only when they are convinced that each accurately reflects the status of the science. CASAC panel meetings are open to the public.¹² These "closure documents" become part of the record for rulemaking. Thus —

The independent, scientific review committee's recommendations on these issues will not only aid the Administrator and the Congress, but also the courts in judicial review of any national ambient air quality standard or of the Administrator's failure or refusal to set or revise such a standard with respect to any pollutant. [Committee on Interstate and Foreign Commerce, House Rept. No. 95-294 (1977), p. 182]

What the closure letter means is that the CASAC panel members agree that the criteria document and the staff paper provide an adequate scientific basis for regulatory decisionmaking. Using formulaic sentences, a closure letter for a criteria document typically reads:

At the September 1995 meeting the Panel came to closure on the Criteria Document. It was the consensus of the Panel members that the Criteria Document provides an adequate review of the available scientific data and relevant studies of ozone and related photochemical oxidants. The document is quite comprehensive and will provide an adequate scientific basis for regulatory decisions on ozone and related photochemical oxidants based on available information. [CASAC Closure on the Air Quality Criteria for Ozone and Related Photochemical

¹²CASAC is subject to the Federal Advisory Committee Act (5 U.S.C. App. 2) which governs public accessibility to committee meetings and products.

Oxidants, letter, from Dr. George T. Wolff, Chair, to Honorable Carol M. Browner, Administrator, EPA (November 28, 1995)]

A closure letter for a staff paper typically says:

It was the consensus of the Panel that although our understanding of the health effects of ozone is far from complete, the document provides an adequate scientific basis for making regulatory decisions regarding a primary ozone standard. [CASAC Closure on the Primary Standard Portion of the Staff Paper for Ozone, letter, from D. George T. Wolff, Chair, to Honorable Carol M. Browner, Administrator, EPA (November 30, 1995)]

The Administrator's Decision

... [I]n the judgment of the Administrator ... [CAA, §109(b)(1)]

The CAA specifies that the Administrator shall use her “**judgment ..., based on [the] criteria [document] and allowing an adequate margin of safety**” to determine the NAAQS “**requisite to protect the public health**” [CAA, §109(b)(1)]. Thus the decision involves weighing of the scientific evidence, collected and analyzed in the criteria document, of the policy options laid out in the staff paper, and of the comments of CASAC — following the criteria dictated in the CAA.

EPA's interpretation of the criteria has been the subject of various challenges. One key issue arose from litigation that actually concerned another part of the CAA; the dispute led to amendments in 1977 that clarified provisions relating to NAAQS. This landmark case concerning the appropriate criteria for air quality regulatory judgments is *Ethyl Corp. v. EPA*. A 3-judge panel, voting 2-1, invalidated the Administrator's regulation of lead in fuels based on § 211 (regulation of fuels) of the CAA [No. 73-2205 (D.C. Cir. Jan. 28, 1975)]. The decision hinged on the burden of proof the Administrator had to meet in order to justify the proposed standard, with the majority holding that the Administrator had to show actual harm rather than the threat or risk of harm. Subsequently, the initial decision was vacated and the U.S. Court of Appeals granted a rehearing en banc; the full court upheld the Administrator's regulations on a 5-4 vote, holding that §211 states a merely precautionary standard — i.e., does not require actual harm.

Even though vacated, the initial *Ethyl* decision raised issues affecting all clean air standards setting that were directly addressed in the 1977 Amendments to the CAA.¹³ In its report on the bill amending the CAA, the House Committee on Interstate and Foreign Commerce identified six issues raised by the case that “*required further congressional clarification*”:

¹³ This discussion, including the quotations, are from U.S. Congress, House, Committee on Interstate and Foreign Commerce, *Clean Air Act Amendments of 1977*, House Rept. No. 95-294, to accompany H.R. 6161 (95th Congress, 1st session) (Washington, D.C.: U.S. Govt. Print. Off., 1977), pp. 43-51.

(1) whether the Administrator could “act to prevent harm before it occurs or should he be authorized to regulate an air pollutant only if he finds actual harm has already occurred”;

(2) whether the Administrator could assess risks or only “make findings of past fact”;

(3) whether the Administrator could consider the cumulative risk of a pollutant from multiple sources, or only the risk from the single class of sources being regulated;

(4) whether different standards of proof apply to different sources;

(5) whether “protection of public health” referred only to healthy normal adults or included “susceptible individuals within the exposed population”; and

(6) whether a “*Court’s standard of review of informal rulemaking by the Administrator to protect public health be whether he has relied on conclusive or indisputable facts or whether he has reached reasonable conclusions which are rationally justified.*”

To resolve these issues, the Committee added language amending the act, using “*a standardized basis for future rulemaking to protect the public health: the Administrator may regulate a pollutant, emissions of ‘which in his judgment cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.’ This same basic formula*” was used in the several standards-setting provisions of the Act, including sections 108 (criteria for NAAQS), 111 (new source performance standards), 112 (hazardous air pollutants), 202 (motor vehicle emission standards), 211 (regulation of fuels and fuel additives), and 231 (aircraft emissions), as well as subtitle B of Title I (ozone and stratospheric protection).

In using this language in amending the act, as discussed in the report on the bill, the Committee intended —

(1) To emphasize the preventative or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs ...;

(2) To authorize the Administrator to weigh risks and make reasonable projections of future trends ...;

(3) To assure consideration of the cumulative impact of all sources of a pollutant in setting ambient and emission standards, not just the extent of the risk from the emissions from a single source or class of sources of the pollutant; ...

(4) To provide the same standard of proof for regulation of any air pollutant ...;

(5) To assure that the health of susceptible individuals, as well as healthy adults, will be encompassed in the term ‘public health,’ regardless of the section of the act under which the Administrator proceeds; and

(6) To reflect awareness of the uncertainties and limitations in the data which will be available to the Administrator in the foreseeable future to enable him to execute his rulemaking duties under this act, because of the limitations on research resources and the fact that decisionmaking about the risks to public health from air pollution falls on ‘the frontiers of scientific and medical knowledge.’

In short, “*the committee language is intended to emphasize the necessarily judgmental element in the task of predicting future health risks of present action*

and to confer upon the Administrator the requisite authority to exercise such judgment.”

This is not, however, a blank check: “... *the committee does not intend this language as a license for ‘crystal ball’ speculation. The Administrator’s judgment must, of course, remain subject to restraints of reasoned decisionmaking.*”

The Evidence.

...[B]ased on such criteria [document] ... [CAA, §109(b)(1)]

Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on —

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

[CAA, §108(a)(2)]

Each agency shall base its [regulatory] decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation. [Executive Order 12866]

The evidence for a NAAQS decision ultimately resides in the criteria document, the staff paper, and the CASAC letters of closure, plus materials submitted during the public comment period. Ancillary information is included in the Regulatory Impact Analysis (discussed below). Summaries are included in the proposed and final rules as published in the Federal Register. In setting NAAQS, the generic direction of E.O. 12866 to regulatory agencies to base their “decisions on the best reasonably obtainable scientific, technical, economic, and other information...” is constrained by the CAA, which specifies that health protection is to be the criterion in determining the standard.

The Criteria.

Health.

Health is the sole criterion for setting the primary NAAQS. (For a discussion of the issue of considering costs, see below.)

Beside the technical information underlying a health standard,¹⁴ the Administrator must consider several crucial policy issues: These include (1) defining whose health the standard is to protect, given that some people will be more susceptible to pollution than others; (2) defining which health effects of pollution are adverse health impacts to be protected against; (3) evaluating exposure and characterizing risk; and (4) considering what factors to take into account in providing “an adequate margin of safety.” The statute and legislative history provide some guidance on these questions. As they are key elements of the judgment that the Administrator makes in deciding the standard, these questions are more or less explicitly posed in the staff paper.

Sensitive populations. For answering the first question, about whose health a primary standard should protect, the Senate Report on the Clean Air Act Amendments of 1970 provided explicit guidance:

In requiring that national ambient air quality standards be established at a level necessary to protect the health of persons, the Committee recognizes that such standards will not necessarily provide for the quality of air required to protect those individuals who are otherwise dependent on a controlled internal environment such as patients in intensive care units or newborn infants in nurseries. However, the Committee emphasizes that included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment. In establishing an ambient standard necessary to protect the health of these persons, reference would be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.

Ambient air quality is sufficient to protect the health of such persons whenever there is an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to ambient air. [Senate Committee on Public Works, Report No. 91-1196 (1970), p. 10]

Also, as discussed earlier, the Committee on Interstate and Foreign Commerce, in its report language discussing amendments relating to the basis for administrative standards, expressly noted its intent to “assure that the health of susceptible

¹⁴ Controversy about the science underlying the 1997 NAAQS standards contributed to later legislation. A key concern focused on the availability of raw data to assess the scientific robustness of a study of health effects of air pollution in several cities and of the conclusions drawn. This led to a provision added to P.L. 105-277 regarding public availability of data; see Eric A. Fischer and Genevieve J. Knezo, *Public access to data from federally funded research: OMB Circular A-110 and issues for Congress* (November 18, 1999), CRS Report RL30376, pp. 3-4. Relatedly, a provision was included in P.L. 106-554 to ensure and maximize the integrity of information used by agencies, and to require agencies to provide “mechanisms allowing affected persons to seek and obtain correction of information ...”; see John E. Blodgett, *Environmental Reauthorizations and Regulatory Reform: From the 104th Congress through the 106th* (December 27, 2000), CRS Report 96-949 ENR, p. 6.

individuals, as well as healthy adults, will be encompassed in the term ‘public health,’ regardless of the section of the act under which the Administrator proceeds.”

Adverse health effect. The Clean Air Act does not define the adverse health effects against which NAAQS must protect, nor does the legislative history of the CAA contain much discussion of what constitutes an adverse health effect. The National Commission on Air Quality¹⁵ noted proposals that the Act contain greater specificity, but observed:

any attempt to identify specific types of health effects could inhibit identification of unanticipated effects that should be considered. In addition, most air pollutants affect public health in more than one way. To carry out its responsibilities under the Act, EPA, before making a final decision to set or revise an air quality standard, must have all relevant and reliable scientific information on the full range of possible health effects of a pollutant.¹⁶

Indications of what constitutes an adverse health effect can be found in the distinction between primary and secondary standards and in the definition of hazardous air pollutants. While a primary NAAQS protects health, a secondary NAAQS protects welfare, which includes, by definition, “personal comfort and well-being.” Thus, pollution effects that involve only “personal comfort and well-being” are not health effects that primary standards are directed toward. The definition of a hazardous air pollutant in the 1970 Act is “an air pollutant ... which ... may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness.” Unquestionably, “increase in mortality,” “irreversible” and “incapacitating” signal health effects. Are bouts of coughing or decreased lung functioning adverse health effects? If they are irreversible or incapacitating, the answer would seem clearly “yes.” As a practical matter, if an effect necessitates medical intervention or leads to curtailed activity, such as missing school or work, the answer would seem “yes.” The question of whether an effect is an adverse health effect can be difficult to answer, particularly if the effect appears minor but may cumulate over a lifetime.

Exposure evaluation and risk assessment.

In order to emphasize the precautionary or preventive purpose of the act (and, therefore, the Administrator’s duty to assess risks rather than wait for proof of actual harm), the committee not only retained the concept of endangerment to health; the committee also added the words ‘may reasonably be anticipated’. ...

By its use of the words ‘cause or contribute to air pollution’, the committee intends to require the Administrator to consider all sources of the contaminant which contribute to air pollution and to consider all

¹⁵The National Commission on Air Quality was created by the Clean Air Act Amendments of 1977, §323, to review the Act and to report to the Congress the effects of the Act, alternative ways of controlling air pollution, and any recommended midcourse corrections.

¹⁶National Commission on Air Quality, *To Breathe Clean Air* (Washington, D.C.: 1981), p. 3.1-2.

sources of exposure to the contaminant — food, water, air, etc. — in determining health risk.

Finally, the term ‘in the judgment of the Administrator’ is intended to modify both the ‘cause and contribute to’ phrase and the ‘reasonably may be anticipated’ phrase. [Committee on Interstate and Foreign Congress, *Clean Air Act Amendments of 1977*, Report 95-294 (1970), p. 51.]

As indicated in the previous discussions of the *Ethyl* and *Lead Industries v. EPA* cases, and as emphasized in House Report 95-294, the Administrator may promulgate a NAAQS in “reasonable” anticipation of public health endangerment. The practical effect of this criterion is to allow a “weight of evidence” approach to be used in setting a NAAQS¹⁷; EPA need not prove that adverse health effects have already occurred, nor that the air-borne form of the pollutant solely caused the harm.

Margin of safety. On the question of what constitutes a “margin of safety,” EPA’s Staff Paper on Particulate Matter summarizes the situation as follows:

The U.S. Court of Appeals for the District of Columbia Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified (*Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), cert. denied, 101 S. Ct. 621 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981), cert. denied, 102 S. Ct. 1737 (1982)). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the “margin of safety” requirement by definition only comes into play where no conclusive showing of adverse effects exists, such factors which involve unknown or only partially quantified

¹⁷In rejecting objections to the ozone NAAQS, the D.C. Circuit Court observed: “One final aspect of EPA’s discussion of the primary NAAQS level is relevant here: The Agency’s response to certain comments questioning its reliance on specific field, epidemiological, and clinical studies. According to EPA, the comments ‘did not reflect an integrative assessment of the evidence – the approach CASAC has historically urged [the Agency] to follow – but rather a piecemeal look at each individual study’ [Ozone NAAQS, 62 Fed. Reg. 38,868]. EPA therefore dismissed the comments, arguing that such an incremental critique ‘tends to miss the strength of the entire body of evidence taken together’ [Ibid]. *American Trucking Association, Inc. v. EPA*, 2002 Westlaw 452092 (D.C. Cir. Mar. 26, 2002).

risks have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment (*Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62). [EPA, *Particulate Matter Staff Paper* (1996), pp. II-1 - II-2]

EPA's view, then, is that the "margin of safety" allows the Administrator to take into account the dimensions of the decision that scientific data cannot resolve. This view has also been voiced by the Courts. For example, concerning the ozone NAAQS, the D.C. Circuit Court of Appeals observed, "... EPA must err on the side of caution, just as it did here – setting the NAAQS at whatever level it deems necessary and sufficient to protect the public health with an adequate margin of safety, taking into account both the available evidence and the inevitable scientific uncertainties." *American Trucking Association, Inc. v. EPA*, 2002 Westlaw 452092 (D.C. Cir. Mar. 26, 2002).

Costs.

The question of whether costs or technical feasibility should be taken into account in setting NAAQS has been an enduring debate. The National Commission on Air Quality explained the principle as follows:

The statutory basis for setting national ambient air quality standards does not take economic factors into account. In the Act, Congress recognized that while the levels of air pollution at which public health is affected generally do not vary among different locations, the costs of meeting a specific standard can vary substantially from area to area, depending upon the severity of the pollution. Thus, if a national air quality standard were based in part on the costs of complying with it, the high costs of meeting the standard in a few heavily polluted areas could result in the standard's being set at a less protective level than is achievable in a reasonable, economic fashion in other areas. The health benefits of good air quality and the economic, social, energy, and other costs of meeting health-based standards can be balanced more effectively and appropriately when control programs are established for particular areas than when national primary standards are set.¹⁸

The concept of deferring cost considerations until the implementation of standards, rather than incorporating them in standards-setting, arose early in the evolution of the CAA. The Senate Report on the Air Quality Act of 1967 affirmed the primacy of health protection in setting NAAQS:

Considerations of technology and economic feasibility, while important in helping to develop alternative plans and schedules for achieving goals of air quality, should not be used to mitigate against protection of the public health and welfare. [Senate Committee on Public Works, Report No. 403 (1967), pp. 28-29]

¹⁸National Commission on Air Quality, *To Breathe Clean Air* (Washington, D.C.: 1981), p. 3.1-2.

Subsequently, in bringing to the floor the Senate bill that became the Clean Air Act Amendments of 1970, Senator Muskie repeated that language and called it a “warning” that had been ignored by those who sought to compromise health standards because of costs:

That warning ... has been on the books of this committee for 3 years, for all to read.

Contrary to this intent, these [cost and feasibility] considerations have been used as arguments to compromise the public health. Therefore, the committee has made explicit in this bill what is implicit to standards designed to protect our health. That concept and that philosophy are behind every page of the proposed legislation.

The first responsibility of Congress is not the making of technological or economic judgments — or even to be limited by what is or appears to be technologically feasible. Our responsibility is to establish what the public interest requires to protect the health of persons.

[Senator Muskie, debate on the National Air Quality Standards Act of 1970 (*Congressional Record*, September 21, 1970, pp. 32901-02)]

The question of taking costs into account in setting NAAQS was litigated in the case of the lead NAAQS. The D.C. Circuit Court’s decision was unambiguous:

... [T]he statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under Section 109.

... Section 109(b) speaks only of protecting the public health and welfare. Nothing in its language suggests that the Administrator is to consider economic or technological feasibility in setting ambient air quality standards.

The legislative history of the Act also shows the Administrator may not consider economic and technological feasibility in setting air quality standards; the absence of any provision requiring consideration of these factors was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals. [*Lead Industries Association v. Environmental Protection Agency*, 647 F.2d 1130 (D.C. Cir. 1980)]

The issue of costs recurred following the 1997 ozone and PM_{2.5} NAAQS. Among the many comments submitted on the proposed rules were objections that the EPA had not considered costs. EPA responded to these comments at some length, arguing that costs should not be considered in setting the NAAQS.¹⁹ EPA’s position was challenged in court, and again the D.C. Circuit Court was explicit:

¹⁹ See, for example, EPA, “Cost Considerations,” *National Ambient Air Quality Standards for Ozone; Final Rule*, 62 *Federal Register* 38878-38883 (July 18, 1997).

As this court long ago made clear, in setting NAAQS under §109(b) of the Clean Air Act, the EPA is not permitted to consider the cost of implementing those standards. [*American Trucking Associations v. U.S. E.P.A.*, 175 F.3d 1027 (D.C. Cir. 1999)]

This holding was among those appealed to the Supreme Court, which unanimously upheld the D.C. Circuit Court’s ruling on this point. The Supreme Court stated:

Section 109(b) does not permit the Administrator to consider implementation costs in setting NAAQS. [*Whitman v. American Trucking Associations, Inc.* 531 U.S. 457 (2001).]

Promulgating NAAQS

The procedural steps for promulgating or revising NAAQS are set forth in the CAA itself — not, as is usual elsewhere, in the Administrative Procedure Act.²⁰ Affecting this process to varying degrees are several other statutory requirements affecting regulations, notably the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and the Small Business Regulatory Enforcement Fairness Act. Also affecting the process are executive mandates, notably Executive Order 12866, Regulatory Planning and Review, and Executive Order 12848, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.

The Administrative Rulemaking Process

For numerous CAA rulemakings, including the process for promulgating or revising CAA rules, §307 of the CAA modifies the procedures of the Administrative Procedure Act governing rulemaking. The process is codified at 42 U.S.C. 7607(d). In general, the procedures require EPA to establish a “docket” that contains all the crucial elements of the rulemaking, that is open to public inspection, and that represents all the information available for the Administrator’s decision. (An additional provision allows evidence not in the docket to be considered in certain cases when the omission was “reasonable.”) The key steps of the rulemaking include: (1) notice of the proposed rulemaking, (2) a period available for public comment, (3) promulgation of the rule, which shall include responses to significant comments on the proposal, and (4) an opportunity for judicial review and challenges to the procedural determinations.

²⁰The Clean Air Act Amendments of 1977, adding §307 to the CAA: the reasons for the changes from the Administrative Procedures Act and their intent are discussed at length in U.S. Congress, House, Committee on Interstate and Foreign Commerce, *Clean Air Act Amendments of 1977*, House Rept. No. 95-294, to accompany H.R. 6161 (95th Congress, 1st session) (Washington, D.C.: U.S. Govt. Print. Off., 1977), pp. 318-325.

Notice of Proposed Rulemaking.

... [T]he Administrator shall publish, simultaneously with the issuance of such criteria [document] and information, proposed national primary and secondary ambient air quality standards [CAA, §109(a)(2)]

... [N]otice of proposed rulemaking shall be published in the Federal Register, ... shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment The notice of proposed rulemaking shall also state the docket number, the location ... of the docket, and the times it will be open to public inspection. [CAA §307(d)(3)]

As an illustration of the process, on June 12, 1996 EPA published an “Advance Notice of Proposed Rulemaking (ANPR) for National Ambient Air Quality Standards for Ozone and Particulate Matter” (61 *Federal Register* 29719-2925). This ANPR outlined the basis for EPA having to make the decision, identified the key documents, and indicated the major options under consideration. The Proposed Rules on ozone and PM were released November 27, 1996, and published December 13 (61 *Federal Register* 65638-65872). Each laid out the proposed decision, requested public comment generally and on specific options, told where and how to access the docket, and provided for a 60-day public comment period (later extended 21 days, until March 12, 1997).

Public Comment.

... [A]fter a reasonable time for interested persons to submit written comments thereon [CAA, §109(a)(1)(B)]

In promulgating a [NAAQS], ... (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments [CAA, §307(d)(5)]

In the case of the ozone and particulate matter NAAQS proposed by EPA in December 1996, the Agency received over 25,000 comments during the public comment period. Also, EPA held 4 public hearings.

Promulgation of the Rule.

...[A]fter a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) [the Administrator] shall by regulation promulgate such proposed national ambient air quality standards with such modifications as he deems appropriate. [CAA, §109(a)(1)(B)]

(A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose ... and (ii) an explanation of the reasons for any

major changes in the promulgated rule from the proposed rule. (B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period. [CAA, §307(d)(6)]

The ozone and particulate matter final decisions were signed by the Administrator on July 16, 1997 and published on July 18, 1997 (62 *Federal Register* 38652-38896). Each final rule contained lengthy discussions of issues raised by commentators and the EPA's final disposition of them.

Regulatory Impact Assessments.

Costs and Benefits — Executive Order 12866.

Each agency shall assess both the costs and the benefits of the intended regulation

For ... a significant regulatory action ... the agency shall ... provide ... (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits; (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment, together with, to the extent feasible, a quantification of those costs; and (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation....

[Executive Order 12866, 58 *FR* 51735 (4 October 1993)]

EPA has concluded that NAAQS reviews are “significant” regulatory actions²¹ requiring preparation of a Regulatory Impact Analysis (RIA). However, EPA also explicitly states that “Because judicial decisions make clear that cost cannot be considered in setting NAAQS, the results of the draft RIA have not been considered in developing this proposal” [National Ambient Air Quality Standard for Ozone: Proposed Decision, pp. 157-158].

The 1996 ozone and PM NAAQS proposals are the first NAAQS rulemakings undertaken since enactment of the Unfunded Mandates Reform Act (UMRA) and the Regulatory Flexibility Act (RFA). While EPA concluded that the proposals were

²¹ E.O. 12866 defines “significant regulatory action” to include a rule that may “have an annual effect on the economy of \$100 million or more”

“significant regulatory actions” as defined by E.O. 12866, EPA concluded that the proposals do not trigger the regulatory analysis provisions of UMRA or RFA.

Unfunded Mandates — Unfunded Mandates Reform Act.

Unless otherwise prohibited by law, before promulgating any general notice of proposed rulemaking that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement containing--

... a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate, including the costs and benefits to State, local, and tribal governments or the private sector, as well as the effect of the Federal mandate on health, safety, and the natural environment and ... a description of the extent of the agency's prior consultation with elected representatives ... of the affected State, local, and tribal governments [Unfunded Mandates Reform Act of 1995, §202(a)]

On the issue of unfunded mandates, EPA concluded:

As indicated previously, EPA cannot consider in setting a NAAQS the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. Accordingly, EPA has determined that the provision of sections 202, 203, and 205 of the UMRA do not apply to this proposed [NAAQS] decision. The EPA acknowledges, however, that any corresponding revisions to associated State implementation plan requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA will address unfunded mandates as appropriate when it proposes any revisions to 40 CFR parts 51 and 58. [Proposed Decision: Particulate Matter, 61 FR 65670 (December 13, 1996)]

However, in its PM RIA, EPA does prepare a governmental entities analysis. According to EPA, “This ... is not an unfunded mandates analysis, but provides estimates of the potential budgetary impact of the control measures used in the control strategy-cost analysis affecting State and local government agencies.” EPA notes that it “will be useful in guiding future implementation activities....” [PM RIA, p. 8-20]

EPA’s denial that it had to prepare an unfunded mandates analysis (regulatory impact statement) was challenged in court as part of *American Trucking Associations v. U.S. E.P.A.* The D.C. Circuit Court noted, however, that the Unfunded Mandates Reform Act explicitly states that a failure to prepare an impact analysis “shall not be used as a basis for staying, enjoining, invalidating or otherwise affecting [an] agency rule” [UMRA, § 1571]. Further, the court held that “the failure to prepare a regulatory impact statement does not render the NAAQS arbitrary and capricious.”

[*American Trucking Associations v. U.S. E.P.A.*, 175 F.3d 1027 (D.C. Cir. 1999), modified on other grounds, 195 F.3d 4 (D.C. Cir. 1999). This issue was not addressed in the appeal to the Supreme Court, see 531 U.S. 457 (2001).]

Small Business — Regulatory Flexibility Act.

Whenever an agency is required ... to publish general notice of proposed rulemaking for any proposed rule, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities.... [5 U.S.C. §603(a)]

When an agency promulgates a final rule ..., after being required ... to publish a general notice of proposed rulemaking, the agency shall prepare a final regulatory flexibility analysis.... [5 U.S.C. §604(a)]

Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. [5 U.S.C. §605(b)]

On the issue of assessing the impact of regulations on small businesses, EPA said the ozone and PM proposed NAAQS —

will not have a significant economic impact on small entities within the meaning of the RFA. Instead, it will establish a standard of air quality that other Act provisions will call on states (or in case of state default, the federal government), to achieve by adopting implementation plans containing specific control measures for that purpose. In other words, state (or federal) regulations implementing the NAAQS might establish requirements applicable to small entities, but the NAAQS itself would not. For these reasons, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.” [National Ambient Air Quality Standard for Ozone: Proposed Decision, pp. 163-164].

EPA nevertheless concedes interest in the “potential impact” of the NAAQS and notes that discussion of those impacts are included in the RIA. In the RIAs, EPA performs a “Screening Analysis” to “evaluate small entity impacts.” This identifies impacts on industries classified by SIC codes.

Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter —

(1) a covered agency shall notify the Chief Counsel for Advocacy of the Small Business Administration and provide the Chief Counsel with information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected;

(2) not later than 15 days after the date of receipt of the materials described in paragraph (1), the Chief Counsel shall identify individuals representative of affected small entities for the purpose of obtaining advice

and recommendations from those individuals about the potential impacts of the proposed rule;

(3) the agency shall convene a review panel for such rule consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel;

(4) the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule, collect advice and recommendations of each individual small entity representative identified by the agency after consultation with the Chief Counsel....

(5) not later than 60 days after the date a covered agency convenes a review panel pursuant to paragraph (3), the review panel shall report on the comments of the small entity representatives and its findings ...; and

(6) where appropriate, the agency shall modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required. [Small Business Regulatory Enforcement Fairness Act of 1996, §244]

On the same basis that it decided the Unfunded Mandates and the Regulatory Flexibility Act requirements did not apply when setting NAAQS, EPA concludes “that the small-entity provisions in Section 244 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) do not apply.” [National Ambient Air Quality Standard for Ozone: Proposed Decision, p. 164] And similarly, EPA says it “intends to fulfill the spirit of SBREFA on a voluntary basis” by working with the Small Business Administration to hold panel exercises to solicit comments and advice from representatives of small entities.

As part of *American Trucking Associations v. U.S. E.P.A.*, this certification that SBREFA did not apply was challenged. However, the D.C. Circuit Court found “incontestable” EPA’s argument that setting a NAAQS has no direct impact on small businesses because the states, through the SIP plan process, determine what sources will be affected. Thus the court concluded that “EPA properly certified that its NAAQS would not have a significant impact on a substantial number of small entities.” [*American Trucking Associations v. U.S. E.P.A.*, 175 F.3d 1027 (D.C. Cir. 1999), modified on other grounds, 195 F.3d 4 (D.C. Cir. 1999)]. This issue was not addressed in the appeal to the Supreme Court, see 531 U.S. 457 (2001).]

Other Regulatory Impact Assessments .

Besides the regulatory impact assessments required by the statutes discussed above, provisions of the Paperwork Reduction Act may be triggered by reporting requirements. In the ozone and PM proposed rules, EPA said that this issue would arise only in implementation.

Also, Executive Order 12848, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, requires each federal agency to identify and address, as appropriate, disproportionate adverse health and environmental impacts of programs, policies, and activities on minorities and low-income populations. Again, EPA indicates that analysis of effects on minorities and

low-income populations would be appropriately examined in preparation of RIAs in the implementation process.²²

Consultations — Office of Management and Budget; Other Departments and Agencies.

The drafts of ... rules submitted by the Administrator to the Office of Management and Budget for any interagency review process ..., all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket [CAA, §307(d)(4)(B)(ii)]

To the extent permitted by law, OMB ... shall be the entity that reviews individual regulations [Executive Order 12866]

EPA's NAAQS decisions are subject to this OMB review: "In view of its important policy implications, this proposal has been judged to be a 'significant regulatory action' within the meaning of the Executive Order, and EPA has submitted it to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public docket and made available for public inspection..." [National Ambient Air Quality Standard for Ozone: Proposed Decision, p. 157]. Apparently no changes were made on this basis, however.

Likewise, drafts of the proposed and final rule are circulated for review to other departments and agencies. In cases of substantive controversy, as with the ozone and PM_{2.5} NAAQS, the issue may go to the White House for final adjudication.

Judicial Review

A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, ... may be filed only in the United States Court of Appeals for the District of Columbia. ... Any petition for review ... shall be filed within sixty days from the date notice of such promulgation ... appears in the Federal Register [CAA, §307(b)(1)]

EPA's NAAQS rulemaking is subject to several statutory procedural requirements, compliance with which is subject to judicial review. The basic framework is spelled out in the CAA, §307(d), [42 U.S.C. §7607(d)] and details the requirements for public notice and participation in the process. The final rule cannot be based, in whole or part, on any information or data which have not been placed in the rulemaking docket as of the date of its final promulgation. The final rule must be accompanied by a statement of basis and purpose which includes a summary of the factual data upon which the rule is based, the methodology used in obtaining and analyzing the data, the major legal interpretations, and policy considerations

²²RIA for Proposed Particulate Matter Ambient Air Quality Standard (December 1996), p. 8-26.

underlying the remaking decision. The statement must also contain the agency's response to each of the significant comments, criticisms, and new data submitted in written and oral presentations during the comment period. Courts have also indicated that they will look at the alternatives the agency considered (or believes it should have considered) in assessing necessary compliance. On appeal the court may reverse the rulemaking action if it finds it to be "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law," a standard by which the courts assess the rule's reasonableness and rationality based on review of the rulemaking record taken as a whole.

The first suits challenging the ozone and PM NAAQS were filed in the D.C. Circuit Court of Appeals on July 18, 1997, the day the final rules appeared in the *Federal Register*. During 1997 a total of 38 suits were filed for judicial review of various aspects of the ozone and PM NAAQS. These suits were consolidated in *American Trucking Associations v. U.S. E.P.A.*, argued December 17, 1998, and decided May 14, 1999 [175 F.3d 1027 (D.C. Cir. 1999)]. Various parts of that decision were then appealed to the U.S. Supreme Court, argued November 7, 2000, and decided February 27, 2001 [*Whitman, Administrator of Environmental Protection Agency, et al. v. American Trucking Associations, Inc., et al.*, 531 U.S. _____ (2001)]. While the Supreme Court decided several aspects of the case – including that the CAA constitutionally delegated authority to EPA and that costs could not be taken into account in setting NAAQS, it remanded the question of the validity of the standards to the D.C. Circuit Court. The Circuit Court issued its ruling on March 26, 2002, upholding EPA's particulate and ozone standards.

For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b) [... if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities], 608(b), and 610 in accordance with chapter 7. [5 U.S.C. §611(a)(1)]

EPA's decisions that requirements of the Small Business Regulatory Enforcement Fairness Act, the Regulatory Flexibility Act, and the Unfunded Mandates Act do not apply to the ozone and PM NAAQS were challenged. These were among the suits consolidated in *American Trucking Associations v. U.S. E.P.A.* As previously noted, the D.C. Circuit Court of Appeals upheld EPA's position.

Congressional Review

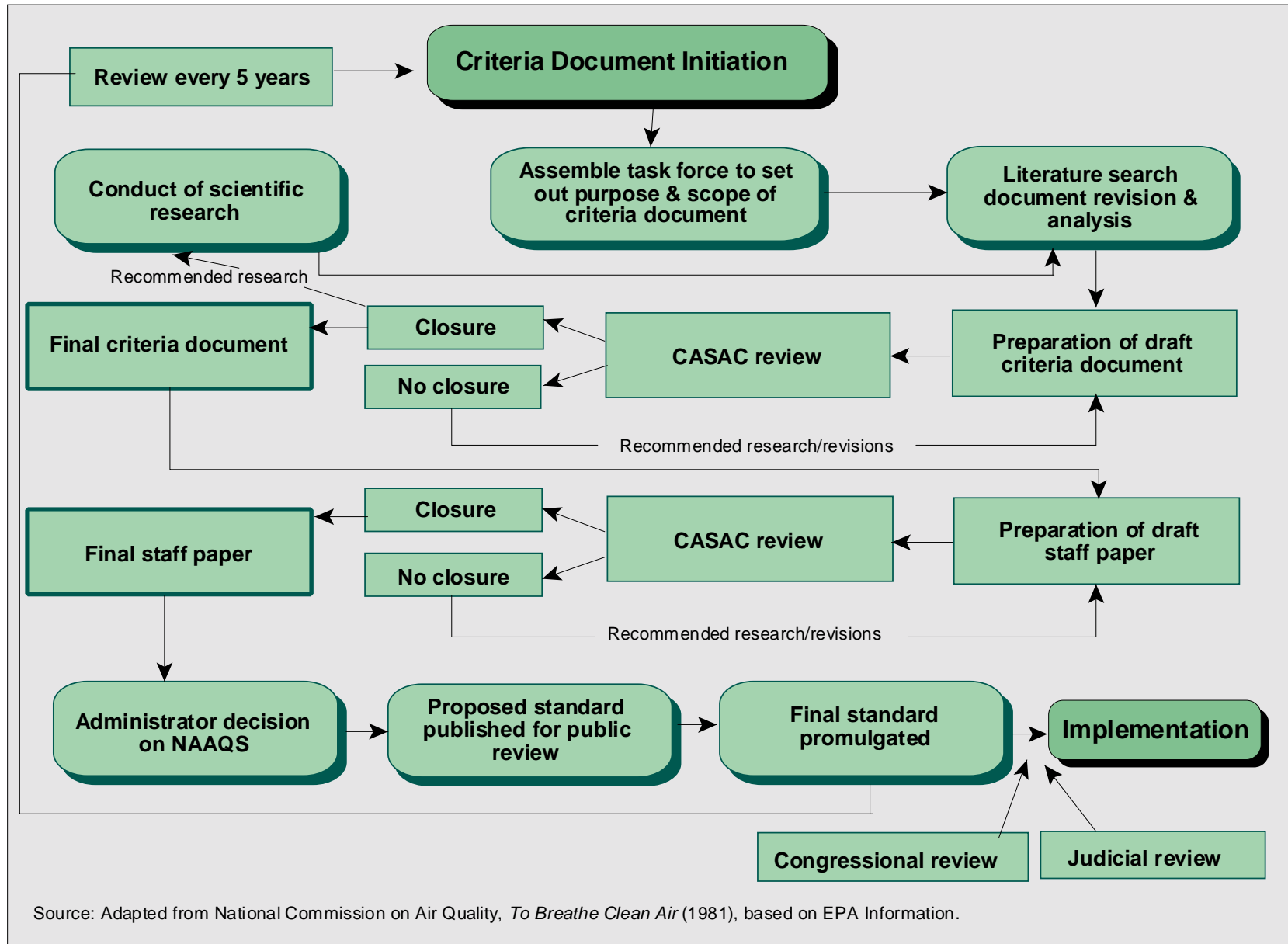
Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress ... a report

A rule shall not take effect ..., if the Congress enacts a joint resolution of disapproval [5 U.S.C. §801(a)(1)(A), (b)(1)]

EPA's publication of its final decisions on the ozone and PM NAAQS on July 18, 1997, triggered the Congressional Review of Agency Rulemaking provision of SBREFA. Under this provision, Congress could consider a joint resolution of disapproval, with special procedures in the Senate to ensure floor consideration

within 60 legislative days. While the procedure was not invoked, bills to delay the new standards were introduced, including H.R. 1984 and S. 1084, with a hearing held on the latter. No bill to rescind the new NAAQS was reported from committee, however.

Appendix I. The NAAQS-Setting Process



Appendix II: Setting NAAQS — a Typical Chronology (Ozone)

August 1992	Ozone NAAQS review initiated
Summer/Fall 1993	Workshops
Spring 1994	Draft Criteria Document available to public and CASAC
July 20 and 21, 1994	CASAC meetings to review draft Criteria Document
March 20 and 21, 1995	CASAC meetings to review revised draft of Criteria Document; also to review draft sections of Staff Paper
September 19 and 20, 1995	CASAC closure on Criteria Document; also closure on primary standard section of Staff Paper
November 28, 1995	CASAC closure letter on Criteria Document sent to Administrator
November 30, 1995	CASAC closure letter on primary standard section of Staff Paper sent to Administrator
March 21, 1996	CASAC subpanel meeting on secondary standard section of Staff Paper
April 4, 1996	CASAC closure letter on secondary standard section of Staff Paper sent to Administrator
June 12, 1996	EPA publishes Advance Notice of Proposed Rulemaking (ANPR) for Ozone & PM NAAQS
July 25 and August 8, 1996	Public meetings on ANPR
November 27, 1996/ December 13, 1996	Proposed Decision announced/published in <i>Federal Register</i> ; public comment period begins
January 14 and 15, 1997	Public Meetings in four cities on proposal
March 12, 1997	End of public comment period on proposal
Winter/Spring 1997	Congressional hearings on the proposed NAAQS
June 25, 1997	President Clinton endorses the proposed ozone & PM NAAQS, with some modifications
late June 1997	EPA submits proposed final standards to OMB

- July 16, 1997 Administrator signs off on final Ozone & PM NAAQS
- July 18, 1997 Final NAAQS published in *Federal Register*
- July 18, 1997 First suit challenging the final standards filed in the U.S. Court of Appeals for the D.C. District
- September 16, 1997 Ozone & PM rules become effective
- December 17, 1998 *American Trucking Associations v. U.S. E.P.A.* argued before D.C. Circuit Court of Appeals
- May 14, 1999 D.C. Circuit Court of Appeals issues decision
- October 29, 1999 D.C. Circuit Court of Appeals (en banc) denies petition for rehearing
- May 22 and 29, 2000 Supreme Court accepts cert. on appeals by EPA and the U.S. Chamber of Commerce
- November 7, 2000 Oral arguments on *American Trucking Associations v. U.S. E.P.A.* before the U.S. Supreme Court
- February 27, 2001 U.S. Supreme Court issues decision, which among other findings unanimously concluded that costs may not be considered in setting NAAQS, remands issue of adequacy of science for standards to Circuit Court
- March 26, 2002 D.C. Circuit Court of Appeals issues decision, basically upholding EPA's particulate and ozone standards