



Air Quality Standards and Sound Science: What Role for CASAC?

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Specialist in Environmental Policy

April 21, 2008

Congressional Research Service

7-....

www.crs.gov

RL33807

Summary

As the Environmental Protection Agency (EPA) completes its reviews of the ozone, particulate matter (PM), and lead air quality standards—the PM review was completed in September 2006, the ozone review in March 2008, and the lead review is due for completion in September 2008—the Clean Air Scientific Advisory Committee (CASAC), an independent committee of scientists that advises the agency’s Administrator, has been sharply critical of several of EPA’s decisions.

CASAC was established by statute in 1977. Its members, largely from academia and from private research institutes, are appointed by the EPA Administrator. They review the agency’s work in setting National Ambient Air Quality Standards (NAAQS), relying on panels of the nation’s leading experts on the health and environmental effects of the specific pollutants. CASAC panels have a nearly 30-year history of working quietly in the background, issuing what were called “closure letters” on agency documents that summarize the science and the policy options behind the NAAQS. The science and policy documents, written by EPA staff, generally have gone through several iterations before the scientists were satisfied, but, with the issuance of a closure letter, CASAC has in past years removed itself from the process, leaving the final choice of standards to the Administrator.

In 2006, however, CASAC and its 22-member PM Review Panel forcefully objected to the Administrator’s decisions regarding revision of the particulate NAAQS. The committee took the unprecedented steps of writing to the Administrator both after he proposed the standards in January, and after he promulgated them in September. In the latter communication, CASAC stated unanimously that the Administrator’s action “*does not provide an ‘adequate margin of safety ... requisite to protect the public health’ (as required by the Clean Air Act) ...*” (Italics in original)

Within a month of CASAC’s September 2006 letter, the committee’s ozone review panel approved EPA’s policy options Staff Paper, the next-to-last formal step before the Administrator proposed to revise the ozone NAAQS. In doing so, the panel drew a firm line (“There is no scientific justification for retaining the current primary 8-hr NAAQS”), and recommended a range far more stringent than the previous standard. The Administrator promulgated a standard outside of CASAC’s range in March 2008.

At the same time that CASAC panels were speaking out, EPA was conducting a review of CASAC’s role and other aspects of the NAAQS-revision process. A December 7, 2006 EPA memorandum made a number of changes in that process that many argue will diminish the role of CASAC and agency scientists. As the changes have been implemented, CASAC has objected to some of the new procedures and a number of Senators have written the EPA Administrator to express their opposition to the changes. Congress is expected to continue taking an interest in the subject. This report discusses these issues, focusing on the statutory and historical role of CASAC and various proposals for change.

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Introduction

The Role of NAAQS in Air Quality Regulation

Setting National Ambient Air Quality Standards (NAAQS) is an action that is at the core of the Clean Air Act. NAAQS apply to “criteria” pollutants—pollutants that “endanger public health or welfare,” and whose presence in ambient air “results from numerous or diverse mobile or stationary sources.”¹ Six pollutants are currently identified as criteria pollutants.² The EPA Administrator can add to the list if he determines that additional pollutants meet the act’s criteria, or delete them if he concludes that they no longer do so.

NAAQS do not directly regulate emissions. Rather, the primary NAAQS identify pollutant concentrations in ambient air that must be attained to protect public health with an adequate margin of safety; secondary NAAQS identify concentrations necessary to protect public welfare, a broad term that includes damage to crops, vegetation, property, building materials, etc.³

In essence, NAAQS are standards that define what EPA considers to be clean air. Their importance stems from the long and complicated implementation process that is set in motion by their establishment. Once NAAQS have been set, EPA, using monitoring data and other information submitted by the states, identifies a list of areas that exceed the standards and must, therefore, reduce pollutant concentrations to achieve them. State and local governments then have three years to produce State Implementation Plans which outline the measures they will implement to reduce the pollution levels in these “nonattainment” areas. EPA also acts to control many of the NAAQS pollutants wherever they are emitted through national standards for products that emit them (particularly mobile sources, such as automobiles) and emission standards for new stationary sources, such as power plants.

CASAC and NAAQS Revision

Because the understanding of pollution’s effects changes with new research, the Clean Air Act requires that EPA review NAAQS at five-year intervals and revise them as may be appropriate. To ensure that these reviews meet the highest scientific standards, the 1977 amendments to the act required the Administrator to appoint an independent Clean Air Scientific Advisory Committee (CASAC). CASAC has seven members, largely from academia and from private research institutions, who generally serve for two consecutive three-year terms. In conducting NAAQS reviews, their expertise is supplemented by panels of the nation’s leading experts on the health and environmental effects of the specific pollutants that are under review. These panels can be quite large. The recent particulate matter and ozone review panels, for example, had 22 and 23 members, respectively. CASAC, as well as the public, makes suggestions regarding the

¹ Authority to establish NAAQS comes from Section 109 of the act, and the procedures for controlling NAAQS (or “criteria”) pollutants are found throughout Titles I, II, and IV of the act. Pollutants that are less widely emitted are generally classified as “hazardous air pollutants” and are regulated under a different section of the act (Section 112).

² The six criteria pollutants are ozone, particulates, carbon monoxide, sulfur dioxide, nitrogen oxides, and lead. All six were first identified as criteria pollutants subject to NAAQS in the 1970s.

³ The Clean Air Act’s definition of welfare is found in Section 302(h) of the act.

membership of these panels, with the final selections made by EPA. The panels review the agency's work during NAAQS-setting and NAAQS-revision, rather than conducting their own independent reviews.

CASAC panels had a nearly 30-year history of working quietly in the background, advising the agency's staff on NAAQS reviews, and issuing what were called "closure letters" on the agency documents that summarize the science and the policy options behind the NAAQS. Closure letters have been used by CASAC panels to indicate a consensus that the agency staff's work provides an adequate scientific basis for regulatory decisions. The science and policy documents, written by EPA staff, generally have gone through several iterations before the scientists were satisfied, but, with the issuance of a closure letter, CASAC has in past years removed itself from the process, leaving the formal proposal and final choice of standards to the Administrator. Proposal comes in the form of a *Federal Register* notice that triggers a formal public comment period, and the final choice is promulgated in the *Federal Register*, as well, following the review of public comments.

2006: A Pivotal Year

In 2006, the usual pattern of NAAQS reviews was upset by three events. First, as EPA promulgated revisions to the particulate matter (PM) NAAQS, CASAC and its PM Review Panel publicly objected both to the Administrator's decision not to strengthen the annual standard for fine particulates (PM_{2.5}) and to various aspects of his decision regarding larger particles (PM₁₀).⁴ The committee took the unprecedented steps of writing to the Administrator both after he proposed the standards in January, and after he promulgated them in September. In the latter communication, CASAC stated unanimously that the Administrator's action "*does not provide an 'adequate margin of safety ... requisite to protect the public health' (as required by the Clean Air Act)*"⁵ (Italics in original.)

A month after CASAC's challenge to the final particulate decision, CASAC's ozone review panel took an unusually strong stand regarding review of that NAAQS. The panel approved EPA's policy options paper (or "Staff Paper"), the next-to-last formal step before the Administrator proposes revision of the ozone NAAQS, but in doing so it stated, "There is no scientific justification for retaining the current primary 8-hr NAAQS ...," and it recommended a range for the revised standard that would be substantially more stringent than the current standard.⁶ The

⁴ The decisions that CASAC objected to also failed to follow the advice of EPA's Staff Paper, which CASAC had endorsed in letters dated June 6, 2005, and September 15, 2005. See letters of Dr. Rogene Henderson, Chair, CASAC, to Hon., Stephen L. Johnson, Administrator, U.S. EPA, June 6, 2005, at [http://yosemite.epa.gov/sab/sabproduct.nsf/E523DD36175EB5AD8525701B007332AE/\\$File/SAB-CASAC-05-007_unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/E523DD36175EB5AD8525701B007332AE/$File/SAB-CASAC-05-007_unsigned.pdf) and September 15, 2005, at [http://yosemite.epa.gov/sab/sabproduct.nsf/3562FF25F05133FC85257084000B1B77/\\$File/sab-casac-05-012.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/3562FF25F05133FC85257084000B1B77/$File/sab-casac-05-012.pdf). These letters did not use the word "closure," a point of controversy that will be discussed later in this report. For many members of CASAC, the absence of closure in 2005 appears to have been the root of the public controversy over the PM standard in 2006.

⁵ Letter of Rogene Henderson et al. of the Clean Air Scientific Advisory Committee to Hon. Stephen L. Johnson, EPA Administrator, September 29, 2006, available at [http://yosemite.epa.gov/sab/sabproduct.nsf/1C69E987731CB775852571FC00499A10/\\$File/casac-ltr-06-003.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1C69E987731CB775852571FC00499A10/$File/casac-ltr-06-003.pdf). Italics in original. For additional discussion of the PM standard controversy, see CRS Report RL33776, *Clean Air Issues in the 110th Congress: Climate Change, Air Quality Standards, and Oversight*.

⁶ Letter of Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Hon. Stephen L. Johnson, EPA Administrator, October 24, 2006, available at [http://yosemite.epa.gov/sab/sabproduct.nsf/AB290E0DB8B72A33852572120055858F/\\$File/casac-07-001.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/AB290E0DB8B72A33852572120055858F/$File/casac-07-001.pdf).

Administrator proposed a revision generally outside CASAC's range on June 20, 2007, and in March 2008 he promulgated new ozone standards that were outside CASAC's range.⁷

The 2006 actions by CASAC and its ozone and PM review panels were followed in short order by an EPA announcement, December 7, 2006, that it would modify the process for setting and reviewing NAAQS. Under EPA's new procedures, the agency's political appointees⁸ have a role early in the process, helping to choose the scientific studies to be reviewed, and CASAC will no longer have a role in approving the policy Staff Paper with its recommendations to the Administrator. (The Staff Paper will also be renamed, becoming a "Policy Assessment.") CASAC will be relegated to commenting on the paper after it appears in the *Federal Register*, during a public comment period.

The goal, according to agency officials, is to speed up the review process, which has consistently taken longer than the five years allowed by statute. "These improvements will help the agency meet the goal of reviewing each NAAQS on a five-year cycle as required by the Clean Air Act, without compromising the scientific integrity of the process,"⁹ according to the memorandum that finalized the changes. The changes caused concern among environmental groups and some in the scientific community, however, because, they say, they give a larger role to the agency's political appointees and a smaller role to EPA staff and CASAC.

These three events (CASAC's challenge of the PM NAAQS, its panel's unusually forceful stance regarding revision of the ozone NAAQS, and EPA's decision to change the NAAQS review process) have thrust CASAC, heretofore a relatively obscure scientific committee, into the limelight. The developments raise important questions regarding the role of science and scientists in the setting of air quality standards. The Senate Environment and Public Works Committee included CASAC issues among those it considered February 6, 2007, in a hearing on "Oversight of Recent EPA Decisions." The House Oversight and Government Reform Committee plans a hearing on the ozone standard April 24, 2008.

To provide a better understanding of the issues, this report provides a history of the NAAQS-setting process and the role of CASAC since its inception in the late 1970s. It also reviews various proposals for change that have been discussed, including EPA's December 2006 modifications.

⁷ CASAC recommended a primary (health-based) standard in a range of 0.060 to 0.070 parts per million (ppm). The Administrator chose 0.075 ppm. CASAC also recommended a new form of secondary (welfare) standard to protect vegetation and crops. The Administrator, after intervention from the White House, rejected the secondary standard recommendation, as well. For additional discussion, see CRS Report RL34057, *Ozone Air Quality Standards: EPA's March 2008 Revision*.

⁸ As in other executive branch agencies or departments, the senior management of EPA consists of officials appointed by the President and confirmed by the Senate.

⁹ "Process for Reviewing National Ambient Air Quality Standards," Memorandum of Marcus Peacock, Deputy EPA Administrator, to Dr. George Gray, Assistant Administrator, Office of Research and Development, and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation, December 7, 2006, p. 3, available at http://www.epa.gov/ttn/naaqs/memo_process_for_reviewing_naaqs.pdf.

History of the NAAQS-Setting Process

Legislative History

Prior to enactment of the Clean Air Act of 1970, there was no authority for the establishment of national ambient air quality standards. Control of air pollution and standards for air quality were considered primarily a state's right and responsibility.

Beginning in 1963, however, Congress began establishing the framework for what became the NAAQS-setting process. The Clean Air Act of 1963 (P.L. 88-206) and the Air Quality Act of 1967 (P.L. 90-148) directed the Secretary of Health, Education, and Welfare¹⁰ to “develop and issue to the States such criteria of air quality as in his judgment may be requisite for the protection of the public health and welfare.” These criteria were to be issued “after consultation with appropriate advisory committees and Federal departments and agencies,” and were to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on health and welfare...”¹¹ To provide scientific advice, the Surgeon General established a National Air Quality Criteria Advisory Committee (NAQCAC) in March 1968.¹²

Establishment of the NAAQS Process. The air quality criteria were originally intended primarily to assist the states in establishing their own air quality standards; but they survive today as the first step in the establishment of national standards (NAAQS). NAAQS themselves were first required by the Clean Air Act Amendments of 1970 (P.L. 91-604). The 1970 amendments directed the new Environmental Protection Agency (which had taken over the air pollution functions of the Health, Education, and Welfare Department) to promulgate NAAQS for each pollutant for which air quality criteria had already been issued,¹³ and to promulgate NAAQS with respect to any additional air pollutant for which criteria would be issued after the date of enactment.¹⁴

Primary NAAQS, as described in Section 109(b)(1), were to 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.” Secondary standards (which, in practice, are often the same as the primary) were also to be based on the criteria and set at a level “requisite to protect the public welfare from any known or anticipated

¹⁰ At the time, the Environmental Protection Agency had not been established.

¹¹ Section 107 of the Clean Air Act (P.L. 88-206, 1963), as amended by the Air Quality Act of 1967 (P.L. 90-148).

¹² Morton Lippmann, “Role of Science Advisory Groups in Establishing Standards for Ambient Air Pollutants,” *Aerosol Science and Technology*, Volume 6, 1987, p. 101.

¹³ Four months after enactment of this authority, on April 30, 1971, the EPA Administrator established the first NAAQS, simultaneously promulgating standards for six categories of pollutants: particulate matter, photochemical oxidants (principally ozone), hydrocarbons, sulfur oxides, nitrogen dioxide, and carbon monoxide. With some modifications, these NAAQS form the cornerstone of the agency's air pollution regulatory programs today, 37 years later. Three of the standards (for SO₂, NO_x, and CO) have changed little. The PM and oxidant standards have been modified, both in the form and the specified concentration of the pollutants, reflecting the developing understanding of the effects of PM and ozone pollution, but the categories of pollution being regulated have not changed. The hydrocarbon standard was revoked in 1983, but hydrocarbons continue to be stringently regulated (as volatile organic compounds) in order for areas to meet the ozone NAAQS.

¹⁴ Only one additional NAAQs has been issued, for lead, in 1978.

adverse effects” (Section 109(b)(2)). The Administrator was permitted to revise both types of standards.

Establishing Formal Review Requirements: SAB and ERDDAA. To assist the Administrator in setting criteria, the Advisory Committee established by the Surgeon General in 1968 (NAQCAC) was transferred to EPA in 1970, as part of the Reorganization Plan that established EPA, but it had no statutory authority. According to Lippmann, a former Chair of CASAC and perhaps the man most familiar with the history, “EPA did not necessarily feel obliged to follow the advice of the Committee.”¹⁵

Beginning in 1974, EPA reorganized its science advisory structure several times, ultimately abolishing NAQCAC over the strong objections of its chairman and members, and reassigning the members to the agency’s Science Advisory Board (SAB). According to Lippmann, at the time it was abolished, “It had been surveying the contents of all the CDs [Criteria Documents] and was drafting a final report that recommended a complete review and revisions of all the air quality criteria documents.”¹⁶ About this time, the House Science and Technology Committee held hearings and produced an investigative report on a series of EPA studies that were intended to provide an improved health basis for the NAAQS.¹⁷ The report led to provisions in the Environmental Research and Development Demonstration Authorization Act of 1978, enacted in November 1977 (ERDDAA, P.L. 95-155) that required the SAB to review all scientific information on which air quality standards are based.

1977 Clean Air Act Amendments: Deadlines and CASAC. The process of establishing NAAQS, in Section 109 of the Clean Air Act, was also amended in the Clean Air Act Amendments of 1977 (P.L. 95-95), adding two major dimensions. First, in Section 109(d)(1), the act established a more formal requirement for review and revision of the NAAQS, directing the Administrator to review the criteria and standards by December 31, 1980, and at five-year intervals thereafter. For a variety of reasons (lack of resources, inadequacies in draft documents, competing demands on agency managers, and in some cases, a lack of political will), these reviews have generally not taken place on the schedule mandated, but, by establishing a nondiscretionary duty of the Administrator, the 1977 act has allowed citizen suits to force the Administrator to undertake reviews.

Second, in Section 109(d)(2), the amendments required the EPA Administrator to appoint “an independent scientific review committee” (to which EPA gave the name CASAC), requiring that it also complete a review of the criteria and standards by December 31, 1980 and at five-year intervals thereafter, and that it recommend to the Administrator any new NAAQS and revisions of existing criteria and standards as may be appropriate. While CASAC is directed to review the criteria and NAAQS and make recommendations to the Administrator, the Administrator is not under a legal obligation to follow CASAC’s advice. As noted below, however, Section 307(d) of the Clean Air Act requires the Administrator to explain the reasons for any differences from CASAC’s or the National Academy of Science’s recommendations.

¹⁵ Lippmann, previously cited, p. 101.

¹⁶ Ibid.

¹⁷ U.S. House of Representatives. Committee on Science and Technology. *The Environmental Protection Agency Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report*. November 1976.

Thus, in the same year, 1977, Congress gave authority to both CASAC and the SAB to review air quality criteria and NAAQS. EPA resolved this potentially overlapping jurisdiction by making CASAC part of the Science Advisory Board.

There have been no changes to these legislative requirements since 1977.

Specifics of the Statutory Requirements

In Section 108, the Clean Air Act requires the Administrator to provide specific information regarding criteria pollutants, without specifying the form of any required documents. It describes at some length what the criteria shall “reflect” and “include.” In response to this language, EPA has developed what it has called a Criteria Document, whenever it has reviewed or established a new NAAQS. The Criteria Document summarizes the state of scientific knowledge regarding the effects of the pollutant in question.

A second document that EPA has prepared as part of the NAAQS-setting or revision process, the Staff Paper, summarizes the information compiled in the Criteria Document and provides the Administrator with options regarding the indicators, averaging times, statistical form, and numerical level (concentration) of the NAAQS. The Staff Paper has no statutory basis, but it is hard to imagine the setting of a standard without some document or documents that would serve its purpose.

Section 109 of the Clean Air Act makes clear that NAAQS are to be proposed and promulgated as regulations, thus requiring their publication in the *Federal Register*. The procedural requirements are addressed in Section 307(d), which exempts NAAQS promulgation or revision from the requirements of the Administrative Procedure Act, but establishes its own (in most cases, similar) requirements. Section 307(d) requires the establishment of a rulemaking docket; it requires notice of proposed rulemaking in the *Federal Register*, accompanied by a statement of the proposal’s basis and purpose, including a summary of the factual data on which the proposed rule is based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed rule. The statement is required to set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by CASAC and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, provide an explanation of the reasons for such differences.

Section 307(d) also requires that any drafts of proposed and final rules submitted by the Administrator to the Office of Management and Budget (OMB) prior to proposal or promulgation, all documents accompanying those drafts, and all written comments thereon and EPA responses to such comments, be placed in the docket no later than the date of proposal or promulgation.

The promulgated NAAQS, like the proposed rule, must appear in the *Federal Register*. It must be accompanied by a statement of basis and purpose and an explanation of the reasons for any major changes from the proposed rule, as well as a response to each of the significant comments, criticisms, and new data submitted during the public comment period.

Standard-Setting in Practice

In practice, NAAQS standard-setting has not directly followed the path envisioned in the statute. Only one of the six standards (for photochemical oxidants/ozone) was reviewed by December 31, 1980, and none has been reviewed at five-year intervals since that time. Several reviews have been begun, only to languish for years in limbo, with no criteria being issued and no decisions as to standards being made. The agency has rarely had the resources to conduct more than two reviews at a time. Citizen suits have generally been the factor that sets the agency's priorities.

Role of CASAC. As discussed further in later sections of this report, the Clean Air Scientific Advisory Committee has been one of the few exceptions to this record. CASAC has provided much of the discipline to keep the NAAQS process moving and has set high standards for agency reviews. As a result, the completed reviews have generally elicited respect from the scientific community, and have generally survived court challenge.

At the same time, CASAC's role has been somewhat different than that specified by the letter of the statute.¹⁸ Rather than conduct its own independent reviews of a NAAQS, CASAC in practice has fulfilled its obligations by reviewing and evaluating the adequacy of the key documents (the Criteria Document and Staff Paper) prepared by EPA staff as they develop or review a NAAQS.

In conducting these reviews, CASAC has played an important role in the decision-making process: in general, the Administrator has not proposed a revision of a NAAQS until CASAC provides him (or her) what have been called "closure letters," stating its consensus that the Criteria Document and Staff Paper provide an adequate scientific basis for regulatory decisionmaking. The closure letter is not statutorily required; it dates from a June 1979 memorandum presented to CASAC by key officials in EPA's Office of Research and Development, Office of Air Quality Planning and Standards, and the CASAC staff officer.¹⁹ Until the PM review completed in 2006, however, every NAAQS review resulted in closure letters before the Criteria Document and Staff Paper went to the Administrator for decisions on NAAQS revision. As will be discussed further below, this departure from past practice in the 2006 NAAQS for PM was opposed by numerous current and former CASAC members in comments to EPA.²⁰

Staff Paper Recommendations. The recommendations in Staff Papers have tended to provide a range of options, so that the Administrator's choice often fell somewhere within the range discussed. For example, in 1997, when EPA revised the PM standard, the Staff Paper recommended a 24-hour PM_{2.5} standard somewhere in the range of 20 to 65 µg/m³. The

¹⁸ CASAC's establishment by statute, and its modus operandi apparently grew out of the experience of an ad hoc scientific advisory body that helped EPA develop the NAAQS for lead in the 1970s. For the history of this, see Roger O. McClellan, "Comments on National Ambient Air Quality Standards Review Process," March 18, 2006, in U.S. EPA, NAAQS Process Review Workgroup, *Review of the Process for Setting National Ambient Air Quality Standards*, March 2006, Attachment 3-B, pp. 4-5, at http://www.epa.gov/ttn/naaqs/naaqs_process_report_march2006_attachments.pdf, hereafter referred to as "Workgroup Report Attachments." Dr. McClellan chaired the ad hoc lead committee in the late 1970s and has served on or chaired CASAC or its review panels for much of the time since then.

¹⁹ See "Recommended Practices for Involving the Clean Air Scientific Advisory Committee (CASAC) in the Review Process for National Ambient Air Quality Standards," Memorandum from Lester D. Grant, Ph.D., Joseph Padgett, and Terry F. Yosie, p. 2. Memo is undated, but was presented to CASAC June 15, 1979.

²⁰ See the comments of Dr. Philip K. Hopke, Dr. Morton Lippmann, Dr. Joe Mauderly, Dr. George T. Wolff, and Dr. Roger O. McClellan in Workgroup Report Attachments, pp. A-17-18, A-20, A-23, A-27, and McClellan letter pp. 5-6.

Administrator chose $65 \mu\text{g}/\text{m}^3$ as the standard. The Staff Paper also recommended an annual standard of 12.5 to $20 \mu\text{g}/\text{m}^3$. The Administrator chose $15 \mu\text{g}/\text{m}^3$.

On several occasions, the Administrator took no action, despite a Staff Paper recommendation. For example in 1990, a Staff Paper on revision of the lead standard recommended a range of standards from 0.5 to $1.5 \mu\text{g}/\text{m}^3$ (vs. the existing standard of $1.5 \mu\text{g}/\text{m}^3$), a monthly rather than quarterly averaging period, and more frequent sampling. EPA took no action on the recommendations, however, and never formally published a decision.

The sulfur dioxide review completed in 1996 provides a slightly different example in which the agency deviated from Staff Paper recommendations. In this case, the Staff Paper recommended three possible regulatory alternatives: 1) establish a new 5-minute NAAQS; 2) establish a new regulatory program under the general authority of Section 303 of the Clean Air Act; or 3) retain the existing suite of standards, but augment their implementation by focusing on those sources likely to produce high 5-minute peak SO_2 levels. EPA retained the existing standard but has not addressed the augmentation issue.

Early Reports/Memoranda Concerning the NAAQS Process

After the last statutory changes to the NAAQS-setting process in 1977, numerous reports and memoranda discussed CASAC's role and the standard-setting process in general. This section briefly reviews these reports and memoranda, before we turn to the 2006 revisions to the process in the next section.

EPA's 1979 CASAC Memorandum

In a 1979 memorandum entitled "Recommended Practices for Involving the Clean Air Scientific Advisory Committee (CASAC) in the Review Process for National Ambient Air Quality Standards," key officials in EPA's Office of Research and Development and Office of Air Quality Planning and Standards and the CASAC staff officer laid out procedures "to define what CASAC should review, the type of output to result from such reviews, and how these reviews can be accomplished consistent with Congressionally mandated time schedules."²¹ The memo identified six phases of a NAAQS review (planning, preparation of a draft report, internal review, public review, document revision, and CASAC closure); it estimated the time needed for each phase (a total of 285-360 days for all six phases); and it identified where in the process CASAC review and closure would occur. According to CASAC staff, this memorandum was never formally approved, but the procedures, including CASAC "closure" on Criteria Documents and Staff Papers, grew out of its recommendations.²²

²¹ Grant, Padgett, and Yosie memo, p. 2, previously cited.

²² Personal communication, Vanessa Vu, Director, Science Advisory Board Staff Office, U.S. EPA, April 24, 2006.

Memos and Reports in the 1980s

In the 1980s, as EPA began conducting the NAAQS reviews mandated by the 1977 amendments, and as CASAC developed its procedures for NAAQS review, a number of reports and memoranda discussed those procedures. In March 1981, the National Commission on Air Quality, a Congressionally-mandated 13-member bipartisan and multi-stakeholder commission, discussed the setting and revision of NAAQS in its final report.²³ In September 1981, CASAC itself completed a report with recommendations concerning the NAAQS standard-setting process.²⁴ A draft report prepared for EPA's Office of Research and Development in August 1984 focused on the structure of the Criteria Document.²⁵ And, in July 1985, CASAC issued an update report, noting that many of its 1981 recommendations had been successfully implemented, but identifying additional issues to further improve the NAAQS process.²⁶

These reports and memos made a number of recommendations that have resurfaced in the December 2006 revisions to the NAAQS review process. These include repeated conclusions that the Criteria Documents are too long or too encyclopedic and need to be focused on key scientific issues. To improve the focus, CASAC, as early as 1981, called for the identification of critical scientific issues and greater public involvement in the early stages of the NAAQS review process. CASAC, both in 1981 and 1985, also called for increased efforts to develop and incorporate risk assessment methodologies in order to better evaluate and communicate the uncertainties inherent in the analyses.

2006 Agency Review of the NAAQS Process

After the mid-1980s, there was little further discussion of changes to the NAAQS review process until December 2005, when EPA's Deputy Administrator asked the Assistant Administrator for Research and Development and the Acting Assistant Administrator for Air and Radiation to "conduct a top-to-bottom review of the NAAQS process" to determine whether its discretionary (as opposed to statutory) aspects "reflect the most rigorous, up-to-date, and unbiased scientific standards and methods." The letter set forth a series of specific questions regarding the timeliness of the process, consideration of the most recent available science, the distinction between science and policy judgments, and whether changes were necessary to better identify and communicate uncertainties.²⁷ The two Assistant Administrators established a Workgroup of EPA staff to conduct the review and make recommendations.

²³ U.S. National Commission on Air Quality, *To Breathe Clean Air*, Final Report, Washington, D.C., March 1981. The Commission was established by Congress under the Clean Air Act Amendments of 1977 "to make an independent analysis of air pollution control and alternative strategies for achieving the goals of the act."

²⁴ U.S. EPA, Clean Air Scientific Advisory Committee, "Setting Ambient Air Quality Standards: Improving the Process," September 1981.

²⁵ R.M. Dowd & Company for U.S. EPA Office of Research and Development, "Recommendations to Improve the Process of Preparing Air Quality Criteria Documents," Draft, August 1984, 17 p. Richard Dowd served as principal science advisor to the EPA Administrator from 1977 to 1981 and was acting Assistant Administrator for Research and Development in 1980 and 1981.

²⁶ U.S. EPA, Clean Air Scientific Advisory Committee, "Report of the Clean Air Scientific Advisory Committee (CASAC) on Improving the Process for Setting National Ambient Air Quality Standards: An Update," July 1985.

²⁷ See Letter of Marcus Peacock, Deputy Administrator, U.S. EPA, to Dr. George Gray, Assistant Administrator for Research and Development, and Bill Wehrum, Acting Assistant Administrator for Air and Radiation, December 15, 2005, at http://www.epa.gov/ttn/naaqs/naaqs_process_report_report_march2006_attachments.pdf.

The review was essentially completed by April 3, 2006, when the two Assistant Administrators sent the Workgroup's report to the Deputy Administrator.²⁸ The report led to further discussions with CASAC and a public meeting, before the Deputy Administrator announced a decision, December 7, 2006, that the Agency would revise the NAAQS process, largely along the lines suggested in the report.

The Workgroup report reached many of the same conclusions as the 1980s' reviews. As the Executive Summary noted:

Past reviews of the process have addressed a number of issues, including the difficulty EPA has had historically in completing NAAQS reviews at five-year intervals as required by the CAA, resulting in litigation-driven review schedules; the statutory role of the Clean Air Scientific Advisory Committee (CASAC) in providing scientific and policy-relevant advice to the Administrator; concerns about the "encyclopedic" nature of EPA's science assessment documents (referred to as "Criteria Documents") and support for a more integrative synthesis of the science; and general support for the introduction and subsequent evolution of a policy-oriented "Staff Paper" to help bridge the gap between the science presented in the Criteria Document and the policy judgments required of the Administrator in reaching decisions on the NAAQS. While many improvements have come about as a result of these past reviews, some of the same issues remain relevant today, and are addressed again in this process review.²⁹

The report recommended:

- combining planning activities for the Criteria Document (CD), risk/exposure, and policy assessment into one integrated planning document;
- restructuring the CD to be a more concise evaluation, integration, and synthesis of the most policy-relevant science, and writing it in language more accessible to policy-makers, "perhaps in the form of a 'plain-English' executive summary";
- developing a continuous process to identify, compile, characterize, and prioritize new scientific studies;
- developing a more concise risk/exposure assessment document (similar to the risk/exposure chapter(s) now included in Staff Papers);
- to the extent that the recommendations above are implemented, replacing the Staff Paper with a more narrowly focused policy assessment document; and
- working with SAB staff to consider the formation of a CASAC subcommittee on risk/exposure assessment, examining additional measures that can be taken to orient new CASAC panel members, and giving further consideration to the issue of CASAC closure in its review of key documents.³⁰

The first five of these recommendations were adopted in the December 7, 2006 decision memorandum with little change. Most were relatively non-controversial, although some, such as

²⁸ U.S. EPA, NAAQS Process Review Workgroup, *Review of the Process for Setting National Ambient Air Quality Standards*, March 2006 (hereafter, "EPA 2006 Review") at http://www.epa.gov/ttn/naaqs/naaqs_process_report_march2006.pdf.

²⁹ *Ibid.*, p. E-1.

³⁰ *Ibid.*, pp. E-3-4. A more complete discussion of the conclusions and recommendations is found on pp. 30-33.

the continuous process for review of new scientific studies, could require additional resources. Also non-controversial would be better focus of the Criteria Document (renamed the “Integrated Science Assessment”), a recommendation made by virtually every group that has reviewed the subject over the last 30 years.

One of CASAC’s major suggestions, stated in letters to the Administrator dated May 12, 2006 and July 18, 2006, was that the initial step in the review process be the convening of a “science workshop,” at which an invited group of expert scientists would “identify important new scientific findings regarding the pollutant in question.”³¹ EPA staff, CASAC members, and the public would be invited to the workshop, and, prior to it, “CASAC would provide input to the Agency to identify subject-matter experts and key new scientific studies and findings to be discussed.” The December 7 decision memorandum accepted this CASAC suggestion, and, as a result, press reports indicated that CASAC was generally pleased with the final decisions.³²

One potentially more controversial change was the preparation of a separate risk/exposure assessment, and a related recommendation that CASAC consider formation of a separate subcommittee on risk/exposure assessment. In the Workgroup report released April 3, 2006, these recommendations were presented as measures that “could enhance the efficiency and timeliness of the overall NAAQS review process.”³³ In calling for better risk assessment, the 2006 review echoed the recommendations of both the 1981 and 1985 CASAC reviews. Better risk assessment would presumably clarify the policy choices the Administrator faces in making NAAQS decisions. At the same time, it is difficult to see how adding a third significant document to the process would enhance its timeliness, as stated in the report. In its May 12, 2006, letter to the EPA Administrator, CASAC raised this point. Noting that CASAC would now have to “double up” the scientific subject matter to be considered at certain meetings, the CASAC Chair wrote:

Therefore, it was not apparent to us how the suggested alterations would make the NAAQS process more efficient or streamlined. On the contrary, EPA’s proposed process appears to be no less time-consuming and likely more resource-intensive than the current process. Indeed, rather than helping the Agency more-easily achieve its NAAQS reviews for the six criteria air pollutants within the statutorily-mandated five-year period (i.e., per the Clean Air Act Amendments of 1977 codified at 42 U.S.C. § Sec. 7409), the proposed process would seemingly ensure that court-ordered completion dates—the result of external litigation—would continue to be the principal “driver” for key milestones in these NAAQS reviews.³⁴

³¹ These questions would include “low-concentration effects [of the pollutant] on both public health and public welfare; current trends in atmospheric chemistry and pollutant distributions; characterization of both anthropogenic and natural sources of pollutant or precursor emissions; and appropriate risk assessment approaches for this particular pollutant.” See letter of Dr. Rogene Henderson, Chair, CASAC, to Hon. Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, July 18, 2006, at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-July-18-2006/\\$File/CASAC-07-18-06.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-July-18-2006/$File/CASAC-07-18-06.pdf).

³² Dr. Rogene Henderson, CASAC’s Chair, for example, was quoted by *InsideEPA* as “pleased that EPA accepted two recommendations from CASAC as part of changes to the NAAQS review process”—the two changes being the science workshop at the outset of the review and the preparation of a more concise science assessment document, supplemented by an electronic database with more detailed information. See “EPA Adviser Downplays Democrats’ Criticism over New NAAQS Changes,” *InsideEPA Clean Air Report*, December 14, 2006.

³³ EPA 2006 Review, p. 26.

³⁴ Letter of Dr. Rogene Henderson, Chair, CASAC, to Hon. Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, May 12, 2006, at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/\\$File/CASAC-05-12-06.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CASAC-05-12-06/$File/CASAC-05-12-06.pdf).

The December 7, 2006 decision memorandum retained the recommendation for a risk/exposure assessment document, but, rather than call for formation of a separate CASAC subcommittee on risk/exposure assessment (which CASAC “emphatically” opposed in its July 18 letter), agreed to CASAC’s suggestion that risk assessment experts be added to future CASAC review panels.

The Workgroup report’s recommendations concerning the Staff Paper (renamed the “policy assessment document” in the report) are difficult to evaluate. Although the language is somewhat vague, the report’s cover memo appears to recommend the removal of EPA staff and CASAC from the document’s final review, making it a reflection of EPA senior management views instead. The memo says, “We have concluded that it is appropriate for the policy assessment document to reflect the Agency’s views, consistent with EPA practice in other rulemakings.”³⁵ This presumably means the views of the agency’s senior management rather than its staff. On the other hand, the Workgroup report stated:

We recognize that important and complex issues are involved in deciding the scope of such a document, as well as deciding whether such a document would continue to reflect staff views, EPA senior management views, or both, and how that choice may affect the process by which such a document would be reviewed by CASAC and the public.³⁶

The December 7, 2006 decision memorandum reiterates the language of the April 3 recommendation, in stating:

... the Agency will develop a policy assessment that reflects the Agency’s views, consistent with EPA practice in other rulemakings. ... This policy assessment should be published in the *Federal Register* as an Advance Notice of Proposed Rulemaking (ANPR), with supporting documents placed in the rulemaking record as appropriate. The use of an ANPR will provide an opportunity for both CASAC and the public to evaluate the policy options under consideration and offer detailed comments and recommendations to inform the development of a proposed rule.³⁷

A number of observers have interpreted this language to mean that CASAC will review the policy options *after* completion of the document rather than before, diminishing its role in the NAAQS-review process. In its July 18, 2006 letter to the Administrator, CASAC said that it wished to review both a first and second draft version of the policy assessment (PA) document before the issuance of a Notice of Proposed Rulemaking. The December 7 decision memorandum does not address this wish directly, but its choice of language appears to have rejected CASAC’s request. One press account quoted the CASAC Chair as saying, “They will come out with their policy before we have a chance to comment on it.” But she added, “They weren’t taking our advice” even under the old process, at least in the recent PM decision.³⁸ In another press account, she

³⁵ See “Review of Process for Setting National Ambient Air Quality Standards,” Memorandum from George Gray, Assistant Administrator, Office of Research and Development, and William Wehrum, Acting Assistant Administrator, to Marcus Peacock, Deputy Administrator, U.S. EPA, April 3, 2006. The memo is available at http://www.epa.gov/ttn/naaqs/naaqs_process_report_march2006_cover.pdf.

³⁶ EPA 2006 Review, p. 32.

³⁷ “Process for Reviewing National Ambient Air Quality Standards,” Memorandum of Marcus Peacock, Deputy EPA Administrator, to Dr. George Gray, Assistant Administrator, Office of Research and Development, and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation, December 7, 2006, pp. 2-3, available at http://www.epa.gov/ttn/naaqs/memo_process_for_reviewing_naaqs.pdf.

³⁸ Rogene Henderson, CASAC Chair, as quoted in “Greater Role for Nonscientists in EPA Pollution Decisions,” *New York Times*, December 8, 2006, p. A22.

appeared less concerned about the changes to the NAAQS process, however, reportedly saying: “I see it as the role of the CASAC to advise the administrator on which levels will be health protective with an adequate margin of safety. That we have done and that we will continue to do.”³⁹

A general theme in the April 3 recommendations and the December 7 final decision seems to be that the role of EPA senior management in the NAAQS-setting process should be heightened, and that of CASAC lessened. The recommendation for preparation of a single integrated planning document, for example, “would provide an opportunity for early involvement of EPA senior management and/or outside parties in the framing of policy-relevant issues,” according to the Review Workgroup’s March 2006 report.⁴⁰ The new policy assessment document would be reviewed after the document’s publication, despite CASAC’s recommendation that it review a first and second draft. The March 2006 report also suggests: 1) a single CASAC review of the policy assessment document, as opposed to the current iterative process; 2) the apparent discontinuation of CASAC closure on the document; and 3) CASAC’s comments to be solicited along with those of the public.⁴¹

Three recommendations regarding CASAC in the Workgroup report also suggested a less independent role for the Committee. These were:

- that EPA prepare more comprehensive guidance on CASAC’s statutory role, to enhance the orientation of panel members and “increase awareness of the importance of maintaining the distinction between science and policy judgments” in CASAC’s recommendations;
- that further consideration be given by EPA and “perhaps communication with CASAC” regarding the issue of CASAC “closure” on EPA documents; and
- that EPA’s SAB Staff Office consider issues related to the selection and management of CASAC NAAQS review panels.⁴²

These recommendations may have arisen simply from concerns for effectiveness—i.e., they may represent only a concern that the agency better orient new members, make the selection process for review panels more transparent, and review the issue of closure, which was raised by several current and former CASAC members in comments they submitted to the workgroup. But coming in the context of the other recommendations, they raised the possibility that EPA intended to weaken the independence and power of CASAC through a variety of means.

Current and Former CASAC Members’ Views of the NAAQS Process

As part of the 2006 NAAQS process review, EPA solicited comments from current and former CASAC members and from stakeholder groups.⁴³ The most consistent comments concerned the

³⁹ *InsideEPA Clean Air Report*, December 14, 2006, previously cited.

⁴⁰ EPA 2006 Review, p. 31.

⁴¹ *Ibid.*, p. 28.

⁴² *Ibid.*, p. 29.

need to improve the focus of Criteria Documents and the need to reinstate the “closure” procedure.

Criteria Document

Commenters generally agreed that CDs are too encyclopedic, take too long to compile, are too difficult to read, and are not sufficiently focused on research that would inform the NAAQS review process. Commenters had a number of suggestions for improving the process, which are reflected in the Workgroup’s recommendations. EPA’s February 2006 CD, on ozone, was mentioned by several commenters as a vast improvement and a model for future efforts.

Closure

The “closure” issue was raised by 7 of the current or former CASAC members, who generally felt that the lack of closure on the PM Staff Paper (completed in 2005) was a serious and unwarranted break with precedent, and contributed to the controversy over the Administrator’s choice of an annual PM_{2.5} standard. CRS contacted EPA staff to ask for background concerning the change in policy on closure. In particular, EPA was asked if there were a memorandum or guidance document, either from CASAC or from the agency, that explained the new policy.

EPA’s response was that there was, in fact, no change in policy. The current CASAC chair, who assumed the Chairmanship in 2005, simply stopped using the term “closure,” according to the Director of the Science Advisory Board Staff Office. “She is trying to get away from the implication that CASAC ‘approves’ of the document. It’s a semantic difference.”⁴⁴

CASAC commenters appeared to strongly disagree with that assessment. Dr. George Wolff, for example, said:

The recent decision by the Agency to eliminate the need for CASAC closure will shorten the process, but, in my opinion, was a bad decision, and I fear that quality will suffer. The iterative review process leading to closure gave the Agency incentive to produce a document that CASAC would approve. Removing that incentive could lead to inferior products.⁴⁵

Dr. Morton Lippmann stated:

... it is important that any changes made in the process do not weaken the long-established integrity, objectivity, and credibility of the process to the scientific community and interested stakeholders. This needs to be explicitly considered in light of the recent changes in SAB Staff management of CASAC’s modus operandi in relation to its demands for discontinuing the issuance of a formal ‘CASAC closure letter’ on Air Quality Criteria Documents (CDs)

(...continued)

⁴³ EPA summarized these comments on pages 15-20 of the Workgroup’s March 2006 report; the full text of written comments from 12 current or former CASAC members was provided in Attachment 3 to the report; and 4 letters from interested parties (states, environmental groups, and the American Petroleum Institute) appeared in Appendix 4.

⁴⁴ Telephone contact, Vanessa Vu, U.S. EPA, April 24, 2006.

⁴⁵ Wolff, in U.S. EPA, NAAQS Process Review Workgroup, *Review of the Process for Setting National Ambient Air Quality Standards*, March 2006, Attachments, p. A-27, at http://www.epa.gov/ttn/naaqs/naaqs_process_report_march2006_attachments.pdf.

and Staff Papers (SPs) from the CASAC review process. This management decision was unwise⁴⁶

Several of the statements regarding the closure decision show the strong feelings it generated among CASAC members. Dr. Joe Mauderly stated:

One of the reasons given for the recent (apparently successful) move by EPA to relegate CASAC to a reviewer, rather than an approver, of documents is that it slows the process. That is pure balderdash. I cannot recall a single instance over my 15 years of experience with the Committee that CASAC was truly the root cause of significant delay. On the other hand, I can recall multiple instances in which, if CASAC had not the prerogative to “close” on documents, EPA was clearly on track to ignore scientific advice and move forward with inadequate documents or incorrect conclusions.⁴⁷

Dr. Bernard Goldstein added: “EPA’s recent decision tells the scientific community that it is not worth our time to be involved in the EPA advisory process.”⁴⁸

CASAC’s July 18, 2006 letter to the Administrator attempted to resolve the “closure” issue by saying that, in order to avoid any implication that closure meant “approval,” the Committee would go back to the original wording of the 1979 memo in which the term closure was first used. “When the CASAC thinks that the science presented in a particular document is adequate for rulemaking, it will affirmatively state so in the closing paragraph of the final letter to the Administrator regarding the review of that document.” This issue was not addressed in EPA’s December 7, 2006 decision memorandum.

Public Comments and Transparency

A third issue raised by several commenters was a sense that EPA and CASAC do not adequately consider public comments during the preparation of the Criteria Document and Staff Paper, in large part because of the lack of a deadline for submission. For example, Dr. George Wolff stated:

Over the years there have been numerous excellent scientific comments produced by various organizations. Unfortunately, they typically arrive a day or two before the CASAC meeting, which gives the members insufficient time to digest them. ... Some Agency response to the public comment documents should be prepared and provided to CASAC.⁴⁹

On a related note, Dr. Roger McClellan complained that too many of CASAC’s meetings are now being scheduled as teleconferences, of which only a summary (no transcript) is later made available.

Timeliness and Efficiency

There was general agreement that the biggest obstacle to more timely completion of NAAQS reviews was the poor quality of initial CD and Staff Paper drafts that EPA presented to CASAC

⁴⁶ Lippmann, in Workgroup Report Attachments, p. A-20.

⁴⁷ Mauderly, in Workgroup Report Attachments, p. A-23.

⁴⁸ Goldstein, in Workgroup Report Attachments, p. A-12.

⁴⁹ Wolff, in Workgroup Report Attachments, pp. 27-28.

for review. The net result is an iterative (“ping pong”) process in which CASAC requests improvements to the documents and EPA revises them, until, after several iterations, CASAC finally closes on the documents’ adequacy.

Distinguishing Scientific Judgments from Policy Choices and Values

Another area in which EPA asked for comments was on the issue of how to distinguish more clearly scientific conclusions and advice from policy judgments and recommendations. This question produced no consensus. On one hand, Dr. Ellis Cowling and others noted that CASAC is required by the statute to “recommend to the Administrator any new ambient air quality standards.” As Dr. Hopke noted, in distinguishing between science and policy judgments:

I hearken back to the law which asks the Committee to *recommend* a standard. CASAC has typically left the recommendation to the staff through closure on the SP. Now since closure has been eliminated, it becomes incumbent on the Committee to make a formal recommendation and this will clearly include more than the science. The loss of closure has helped to blur the line between scientific advice and clearly leads to the Committee taking a more active policy role.⁵⁰

On the other hand, Dr. Wolff argued that, particularly in its January 17, 2006 letter regarding the proposed PM standards, “CASAC has clearly overstepped their boundaries and ventured into the policy arena.”⁵¹

Somewhere between these views are the comments of Dr. Rogene Henderson, the current Chair of CASAC, who states:

The Agency should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice. The line between science and policy is not always apparent, and this difference should be made clear in the charge questions given to CASAC.⁵²

A similar point is made by another long-time CASAC member, Dr. Joe Mauderly:

Neither scientists nor policy makers want to draw the line, or to define it or admit to it. CASAC meetings are rife with discussions about how its pronouncements will affect policy, and scientist advocates (on CASAC and its panels, as well as others) game the system to achieve their ideological policy goals. When EPA proposes or promulgates standards, it is reluctant to state clearly how science and policy enter into the decision—it wants to portray that all is based on science. These behaviors are absolutely understandable—most scientists are convinced that they know what’s best for the country, and EPA Administrators don’t want to admit to any motive other than the “best science”....

⁵⁰ Hopke, in Workgroup Report Attachments, p. A-19.

⁵¹ Wolff, in Workgroup Report Attachments, p. A-28.

⁵² Henderson, in Workgroup Report Attachments, p. A-14.

At present, my only suggestion is that the Administrator make explicit (much more so than at present) just how science and policy separately bore on the proposed standard, and how the two were integrated.⁵³

A Consensus Observation

In reviewing the many comments on the NAAQS process, much was found to criticize or to recommend, but perhaps more striking than the criticism was the degree to which commenters appear to believe that the system has worked. As stated by Dr. Bernard Goldstein, a former Chair of CASAC and a former Assistant Administrator of EPA's Office of Research and Development, "... in my teaching of environmental health policy to both public health students and to law students, I routinely present the NAAQS standard-setting process as one that represents an ideal interface between science and regulation."⁵⁴ Dr. Roger McClellan, who, in some respects was critical of the process, stated:

Without question, the CASAC has played a critical role in ensuring that the 'final' criteria documents were of high scientific quality. ... The activities of the CASAC, in my opinion, have been in accord with the language and intent of the Clean Air Act (1977) and consistent over time with the evolution of CASAC practices that have received substantial public and legal scrutiny. The modus operandi has proved successful in helping to ensure that the NAAQSs are science-based.⁵⁵

Dr. Lippmann asked:

Can the Process for Setting NAAQS be Strengthened?

The easy answer is of course it can, and I will address how it can in text that follows. However, it is important that any changes made in the process do not weaken the long-established integrity, objectivity, and credibility of the process to the scientific community and interested stakeholders.⁵⁶

Conclusions

Sections 108 and 109 of the Clean Air Act establish statutory requirements for the identification of NAAQS (or "criteria") air pollutants and the setting and periodic review of the NAAQS standards. But the process used by EPA is as much the result of 37 years of agency practice as it is of statutory requirements. In Section 109, for example, the statute establishes the Clean Air Scientific Advisory Committee to make recommendations to the Administrator regarding new NAAQS and, at five-year intervals, to make reviews of existing NAAQS with recommendations for revisions. In practice, EPA staff, not CASAC, have prepared these reviews, drafting Criteria Documents, which review the science and health effects of criteria air pollutants, and Staff Papers, which make policy recommendations. CASAC's role has been to review and approve

⁵³ Mauderly, in Workgroup Report Attachments, pp. A-24, A-25.

⁵⁴ Goldstein, p. A-11, in Workgroup Report Attachments.

⁵⁵ McClellan, p. 5, in Workgroup Report Attachments.

⁵⁶ Lippmann, p. A20, in Workgroup Report Attachments.

these EPA documents before they went to the agency's political appointees and the Administrator for final decisions.

Under EPA's new procedures, EPA's political appointees have a role early in the process, helping to choose the scientific studies to be reviewed, and CASAC will no longer approve the policy Staff Paper with its recommendations to the Administrator. CASAC's iterative role that refined the EPA Staff Paper conclusions could be eliminated, and the Committee relegated to commenting on the policy paper after it appears in the *Federal Register*, during a public comment period.⁵⁷ The goal, according to agency officials, is to speed up the review process, which has consistently taken longer than the five years allowed by statute. "These improvements will help the agency meet the goal of reviewing each NAAQS on a five-year cycle as required by the Clean Air Act, without compromising the scientific integrity of the process,"⁵⁸ according to the memorandum that finalized the changes. The changes have caused concern among environmental groups and some in the scientific community, however, because, they say, they give a larger role to the agency's political appointees and a smaller role to EPA staff and CASAC.

CASAC's Statutory Role

If Congress chooses to review these new procedures, one issue that it may wish to focus on is the statutory role of CASAC: whether it should play some formal role in approving the Administrator's choice of standards. Under current law, CASAC's role is purely advisory. EPA is not required by the Clean Air Act to follow CASAC's recommendations; the act (in Section 307(d)(3)) requires only that, when the Administrator proposes a new or revised NAAQS in the *Federal Register*, he set forth any pertinent findings, recommendations, and comments by CASAC (and the National Academy of Sciences), and, if his proposal differs in an important respect from any of their recommendations, provide an explanation of the reasons for such differences.

CASAC, in practice, has tended to play a larger role, evaluating EPA staff's analysis of the science and its policy recommendations and withholding formal "closure" on the agency documents until it was satisfied that the documents accurately reflected the state of the science. The statute has never required EPA to have CASAC's approval before proposing or promulgating NAAQS revisions, but, in practice, the need to build a record that it could defend against court challenges has generally led EPA to promulgate standards within the range of CASAC's recommendations.

⁵⁷ Exactly how the new procedure will work was expected to be defined in the current review of the lead NAAQS. On August 24, 2007, however, the U.S. District Court for the Eastern District of Missouri intervened in this process, ordering EPA to issue a staff paper on lead by November 1, 2007, following a schedule the court had previously issued and refused to modify. Thus, EPA has been forced to follow the old NAAQS review process more closely than it intended in the lead NAAQS review. *Missouri Coalition for the Environment v. Johnson*, No. 4:04CV00660 (E.D. Mo. August 24, 2007).

⁵⁸ "Process for Reviewing National Ambient Air Quality Standards," Memorandum of Marcus Peacock, Deputy EPA Administrator, to Dr. George Gray, Assistant Administrator, Office of Research and Development, and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation, December 7, 2006, p. 3, available at http://www.epa.gov/ttn/naaqs/memo_process_for_reviewing_naaqs.pdf.

In 2006, for the first time, the Administrator promulgated standards outside of that range,⁵⁹ and CASAC, in a written response, made clear that it felt the standards did not meet the statutory requirements. That may be the role Congress intended for CASAC, or it may not. On one hand, Congress could conclude that CASAC has overstepped its bounds, in essence judging an Administrator's final decision in contrast to its statutory mandate to make recommendations beforehand. On the other hand, Congress might conclude that the Administrator's judgment should have been constrained to the range of options that CASAC established as being supported by the science.

Judicial Review

The courts are likely to play a role here, as well. Thirteen states, the District of Columbia, electric utilities and other industry groups, groups representing farmers and ranchers, and several environmental groups have challenged the PM standards in court.⁶⁰ Legal challenges to NAAQS are not unusual. In reviewing EPA regulations in the past, courts have often deferred to the Administrator's judgment on scientific matters, focusing more on issues of procedure, jurisdiction, and standing. Nevertheless, CASAC's detailed objections to the Administrator's decisions and its description of the process as having failed to meet statutory and procedural requirements could play a role as these standards are reviewed in court.

The subsequent ozone review, which was completed in March 2008, provides a second example of the Administrator not following CASAC's recommendations.⁶¹ As of this writing, the new standard had not been challenged in court, but it is expected that it will be, giving the courts another opportunity to rule on CASAC's role in the setting of NAAQS.

CASAC's Reaction to the New Procedure

Although the new NAAQS review procedures will change the role that CASAC has historically played, CASAC, at first, appeared less concerned with the changes than some who have advocated on its behalf. When the December 7, 2006 decision memorandum was released, the committee's Chair said CASAC did not plan to issue a formal response. As noted above, in its response to the Workgroup report released in April 2006, the committee had made a number of suggestions, some of which, such as the convening of a science workshop at the outset of the process to better focus the review, were incorporated into the decision memorandum. The memorandum also addressed another of CASAC's major concerns, that the old process spent too much time compiling an encyclopedic review of the literature, much of which had little relevance to the policy questions that needed to be addressed. With respect to EPA taking comments from CASAC at the same time that it considers comments from the public, CASAC's Chair was

⁵⁹ In the Administrator's judgment, the science underlying CASAC's recommendation (regarding the PM_{2.5} NAAQS) was not sufficient, relying primarily on two studies, neither of which "provide[s] a clear basis for selecting a level lower than the current standard...." The Administrator agreed with CASAC that the science shows a relationship between higher levels of PM_{2.5} and an array of adverse health effects, but he maintained that there was too much uncertainty in the analysis to justify lowering the annual standard. See discussion beginning at 71 *Federal Register* 61172, October 17, 2006.

⁶⁰ *American Farm Bureau Federation v. U.S. EPA*, no. 06-1410 (D.C. Cir).

⁶¹ For a discussion, see CRS Report RL34057, *Ozone Air Quality Standards: EPA's March 2008 Revision*.

reported to say, “(S)ome of the members were concerned but most are not, because it doesn’t change CASAC’s ability to comment.”⁶²

In early February 2007, however, reports circulated that CASAC had changed its mind. After its first experience with the new NAAQS review process,⁶³ it was reported that the committee would compose another letter to the EPA Administrator critical of the new process:

Henderson [CASAC Chair Dr. Rogene Henderson] said the staff paper had been based on scientific considerations. With the new process, EPA is “skipping that and going right to options based on management views,” she said. EPA should produce options based on science before having EPA management make recommendations about what they want the standard to be, Henderson said.

Henderson said that when EPA first proposed the NAAQS process changes in response to a memo by Deputy Administrator Marcus Peacock, CASAC had “misunderstood how it would be implemented.”

However, “the full consequences became apparent in the lead meeting,” she said, with panel members concerned about not being able to review staff recommendations. The new process “does not allow CASAC time for appropriate input to evaluate the science,” she said. “And the letter will say how this is not working out,” Henderson said.⁶⁴

Negotiations between CASAC and EPA management followed the February 6-7, 2007 public meeting, with the result that EPA modified its schedule to allow the CASAC Lead Review Panel to review a second draft of EPA’s risk and exposure assessment before the agency’s Policy Assessment was published in the *Federal Register*. This mollified some of CASAC’s concerns, but CASAC has continued to express “serious concerns” about other aspects of the Lead NAAQS review.⁶⁵

In January 2008, CASAC’s concerns (now informed by experience with each step of the new review process) crystallized in a four-page letter to Administrator Johnson. The Committee discussed “significant problems that exist in the latter steps of this new review process,” specifically the absence of a Staff Paper (“a document highly-valued by CASAC for its thorough analysis of the new scientific evidence ..., its presentation of the possible alternatives for the standards ... and, most importantly, its provision of the scientific evidence undergirding those alternatives.”)⁶⁶

The Committee said it had been reassured that the Policy Assessment to be published as an Advance Notice of Proposed Rulemaking (ANPR) would be functionally equivalent to the Staff

⁶² Comment of Dr. Rogene Henderson, CASAC Chair, in “EPA Adviser Plays Down Democrats’ Criticism over New NAAQS Changes,” *Inside EPA Clean Air Report*, December 14, 2006.

⁶³ A CASAC Review Panel met to consider the Lead NAAQS on February 6-7, 2007.

⁶⁴ “Advisory Panel to Recommend Stricter Limit for Agency’s Air Quality Standard for Lead,” *Daily Environment Report*, February 9, 2007, p. A-1.

⁶⁵ See letter of Dr. Rogene Henderson, Chair, CASAC, to Hon. Stephen L. Johnson, Administrator, U.S. EPA, March 27, 2007, at [http://yosemite.epa.gov/sab/sabproduct.nsf/4620a620d0120f93852572410080d786/989B57DCD436111B852572AC0079DA8A/\\$File/casac-07-003.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/4620a620d0120f93852572410080d786/989B57DCD436111B852572AC0079DA8A/$File/casac-07-003.pdf).

⁶⁶ Letter of Dr. Rogene Henderson, Chair, CASAC, to Hon. Stephen L. Johnson, Administrator, U.S. EPA, January 23, 2008, p. 2, at [http://yosemite.epa.gov/sab/sabproduct.nsf/B7E63138A2041A22852573DB005D4E98/\\$File/EPA-CASAC-08-008-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/B7E63138A2041A22852573DB005D4E98/$File/EPA-CASAC-08-008-unsigned.pdf).

Paper, but in practice, in the ongoing review of the Lead NAAQS, it found that the ANPR was “*both unsuitable and inadequate as a basis for rulemaking.*”⁶⁷ The letter states that “there is a stark contrast between the empty and regressive nature of the ANPR—which is not a *true* policy assessment—and the scholarly and complete scientific analyses presented in EPA’s Staff Paper.”⁶⁸

The letter noted that the ANPR asked for comment on options that had already been dismissed on scientific grounds. The result is that, rather than inducing greater efficiency in the review process, it slows down the process “through its illogical contemplation of a *greater* number of options as time progresses.”⁶⁹

While agreeing that there may be a role for an ANPR at the *beginning* of the review process, the letter concludes by reiterating CASAC’s view of its statutory mission in reviewing the policy assessment:

Furthermore, it is essential that this policy assessment document be furnished to the CASAC for peer-review in public advisory meetings, in the same manner as multiple drafts of the Staff Paper were provided to the Committee for review under the previous process. It cannot be overstated that, in order to fulfill its Congressionally-mandated and thus legal role, the Committee needs to conduct a thorough and open evaluation of this “best available science,” i.e., the scientific justification and underlying analyses of the various options for standard-setting that the Agency formerly presented in the Staff Paper—which of course will now include the viewpoints of EPA management. Obscuring or weakening such an independent scientific review would subvert both the vital interests of the CASAC and the public’s confidence in this NAAQS review process—a result that the Agency surely neither intends nor desires.⁷⁰

Congressional Reaction

Responding to the changes at the time of their announcement in December 2006, the incoming Chair of the Environment and Public Works Committee, Senator Barbara Boxer, called them “unacceptable,” and said the committee planned to make them a top priority for oversight in the 110th Congress.⁷¹ (The committee included them among the topics it considered in a February 6, 2007 hearing on “Oversight of Recent EPA Decisions.”) Seven Democratic members of the committee, including Senator Boxer, wrote EPA Administrator Johnson, December 21, 2006, to express their strong opposition to the changes and to ask him to “abandon” them.⁷²

In the following months, congressional attention has generally been on other issues. As the reviews of the PM, ozone, and lead standards progress, however, and as the courts review EPA’s final decisions regarding these standards, there are likely to be continued opportunities for congressional oversight. Thus, the role of CASAC in NAAQS reviews could be the subject of further attention in Congress.

⁶⁷ Ibid., italics in original.

⁶⁸ Ibid., p. 3.

⁶⁹ Ibid.

⁷⁰ Ibid.

⁷¹ Office of Senator Barbara Boxer, “Boxer Statement on EPA’s Politicization of Clean Air Health Standards,” Press Release, December 8, 2006, at <http://boxer.senate.gov/news/releases/record.cfm?id=266781>.

⁷² Office of Senator Barbara Boxer, “Democratic Members of Senate EPW Committee Warn EPA on Air Rollbacks,” Press Release, December 21, 2006, at <http://boxer.senate.gov/news/releases/record.cfm?id=267092>.

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