

TOPICS:

- 1) CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE (CASAC) RECOMMENDATIONS CONCERNING THE PROPOSED NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS) FOR PARTICULATE MATTER
- 2) PROPOSED CHANGES IN THE NAAQS PROCESS

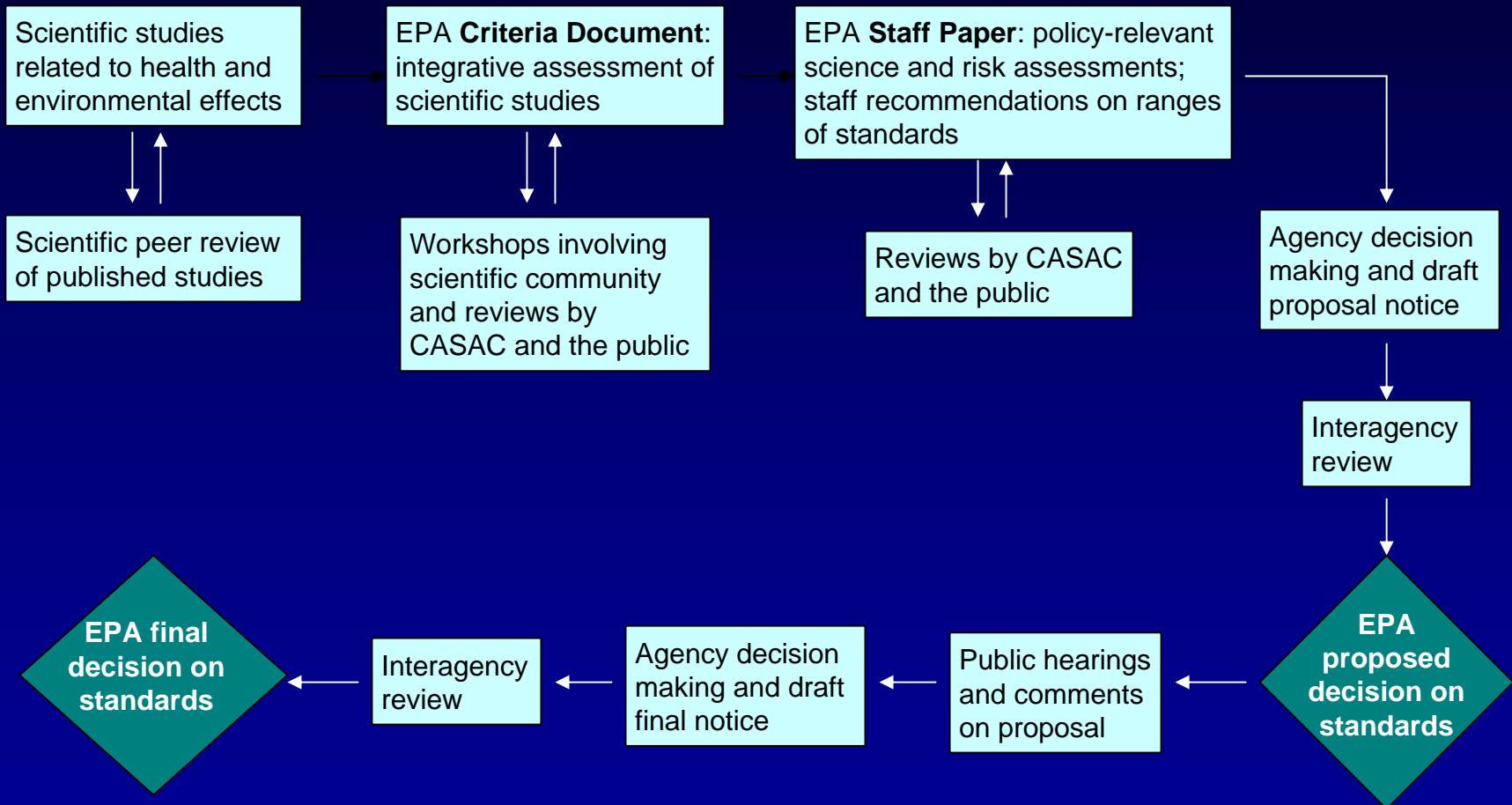
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National Ambient Air Quality Standards

- Clean Air Act requires establishment of National Ambient Air Quality Standards (NAAQS) to protect public health and welfare from the adverse effects of common air pollutants (“criteria pollutants”).
 - “Primary” standards to protect public health.
 - Need to protect sensitive subgroups, but not most sensitive individual.
 - Need to provide “adequate margin of safety.”
 - “Secondary” standards to protect public welfare and the environment (including visibility).
- NAAQS promulgated for 6 common pollutants: ozone, particulate matter, sulfur dioxide, lead, nitrogen dioxide and carbon monoxide.
- EPA required to review (and revise if appropriate) each NAAQS on a 5-year cycle, with input from the Clean Air Act Scientific Advisory Committee (CASAC)

Current NAAQS Process



BACKGROUND

The CASAC, comprised of seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (CAA or “Act”) (42 U.S.C. § 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act. The PM Panel is comprised of the seven members of the chartered (statutory) Clean Air Scientific Advisory Committee, supplemented by fifteen technical experts.

Proposed Primary Annual PM_{2.5} Standard Level:

For this NAAQS level, the Agency has, for the first time, chosen to propose going outside the range of the CASAC-recommended levels. It has proposed to retain the annual standard level at its current level of 15 $\mu\text{g}/\text{m}^3$.

SPECIFIC CASAC RECOMMENDATIONS ON PM NAAQS

- ___The CASAC requests reconsideration of the proposed ruling for the level of the annual PM_{2.5} NAAQS so that the standard is set within the range previously recommended by the PM Panel, *i.e.*, 13 to 14 µg/m³.
- The CASAC also recommends that the proposed 24-hour PM_{10-2.5} primary standard be accompanied by a national monitoring program for PM_{10-2.5} in both urban and rural areas to aid in informing future health and welfare effects studies on rural dusts.
- Moreover, the CASAC strongly recommends expansion of our knowledge of the toxicity of PM_{10-2.5} dusts rather than exempting specific industries (*e.g.*, mining, agriculture).
- Finally, the CASAC requests that the sub-daily secondary standard to protect visibility, as recommended both in the PM Staff Paper and by the CASAC, be favorably reconsidered.

CASAC reiterated and elaborated on the scientific basis for the PM Panel's earlier recommendation, as follows:

First, the Agency's risk assessment indicating reduced health risks at annual PM_{2.5} levels below the current standard was a key component in the PM Panel's recommendation to lower the current annual level. While the risk assessment is subject to uncertainties, most of the PM Panel found EPA's risk assessment to be of sufficient quality to inform its recommendations. The authors of the Agency's risk assessment followed CASAC's advice in conducting extensive sensitivity analyses and in revising the threshold assumptions as published in the final PM Staff Paper. The risk analyses indicated that the uncertainties would increase rapidly below an annual level of 13 µg/m³ — and that was the basis for the PM Panel's recommendation of 13 µg/m³ as the lower bound for the annual PM_{2.5} standard level.

CASAC reiterated and elaborated on the scientific basis for the PM Panel's earlier recommendation (continued)

While the risk analysis is the primary means of determining the effects on risk of changes in the 24-hour and annual PM_{2.5} standards in concert, there is evidence that effects of long-term PM_{2.5} concentrations occur at or below the current annual standard level of 15 µg/m³. Studies described in the PM Staff Paper indicate that short-term effects of PM_{2.5} persist in cities with annual PM_{2.5} concentrations below the current standard. In a Canadian study (Burnett *et al.*, 2000; Burnett and Goldberg, 2003), significant associations with total and cardiovascular mortality were present at a long-term mean PM_{2.5} concentration of 13.3 µg/m³. There were also positive findings in studies in Phoenix, AZ (Mar *et al.*, 1999, 2003) and in Santa Clara County, CA (Lipsett *et al.*, 1997) in which long-term mean concentrations of PM_{2.5} were approximately 13 µg/m³.

Therefore, the CASAC requests reconsideration of the proposed ruling for the level of the annual PM_{2.5} NAAQS so that the standard is set within the range previously recommended by the PM Panel, i.e., 13

Proposed 24-hour PM_{10-2.5} Standards:

The PM Panel is concerned that some of the advice provided may have been misunderstood, as follows:

1. **Monitoring:** Our report of September 15, 2005 indicated that it was essential to monitor coarse thoracic particle concentrations in both rural and urban areas. As stated therein, “It is essential to have data collected on the wide range of both urban and rural areas in order to determine whether or not the proposed UPM_{10-2.5} standard should be modified at the time of future reviews.”
2. **Source of toxic components in coarse thoracic particles:** The preamble to the proposed rule on PM NAAQS cites “specific initial advice from CASAC (Henderson, 2005),” which was “most [PM] Panel members concurred that the current scarcity of information on the toxicity of rural dusts makes it necessary for the Agency to base its regulations on the known toxicity of urban-derived coarse particles.” However, that same report also underscored the associated “need for monitoring thoracic coarse particle levels [in rural areas] and for population-based health-effects studies in those rural areas where it is feasible to conduct such studies.” The CASAC neither foresaw nor endorsed a standard that specifically exempts all agricultural and mining sources, and offers no protection against episodes of urban-industrial PM_{10-2.5} in areas of populations less than 100,000.

Proposed 24-hour PM_{10-2.5} Standards: (continued)

- 3. Secondary PM_{10-2.5} Standards:** As stated in the CASAC's report of September 15, 2005, the CASAC recommends that a secondary PM_{10-2.5} standard be set at the same level as the primary PM_{10-2.5} standard to protect against the various irritant, soiling and nuisance welfare or environmental effects of coarse particles. Since these effects are not uniquely related to urban sources or receptors, the secondary standard should not be limited to urban areas.

Accordingly, the CASAC recommends that the proposed 24-hour PM_{10-2.5} primary standard be accompanied by monitoring of particles in both urban and rural areas to aid in informing future health effects studies on rural dusts. Moreover, the CASAC strongly recommends expansion of our knowledge of the toxicity of rural dusts rather than exempting specific industries (e.g., mining, agriculture). Serious consideration should also be given to a secondary PM_{10-2.5} at a level similar to the proposed primary standard, but without the "urban" geographical constraint.

Proposed secondary PM_{2.5} standard to protect visibility:

To protect visibility, the EPA staff paper, with concurrence of most CASAC members, recommended a sub-daily standard for PM_{2.5} with a level in the 20 to 30 µg/m³ range for a four- to eight-hour (4-8 hr) midday time period with a 92nd to 98th percentile form. The upper end of this range (25-30 µg/m³ and a 92% to 95% form) was considered to be “lenient” in terms of protecting visibility, permitting a relatively high number of days with relatively poor visual air quality. It was suggested as a starting point for a national secondary standard given the uncertainties in both the current science of what is adverse to the public and in the mechanics of setting and operating a new sub-daily standard to protect visibility.

The proposed rule recommended relying on the proposed 24-hour primary standard of 35 µg/m³ as a surrogate for visibility protection, noting through analysis that a percentage of counties with monitors (and the corresponding percentages of populations) not likely to meet the sub-daily secondary standard with a lenient level and form is comparable to those not likely to meet a 24-hour primary standard set at the proposed 35 µg/m³ level. EPA’s proposal to revise the NAAQS for PM also cited limitations in the science and in the available hourly air quality data required for a sub-daily standard.

CASAC members note three cautions of the Agency's proposed visibility standard, which was outside the range recommended in the EPA staff paper and by most of the PM Panel:

1. As both the Staff Paper and the preamble to the proposed rule on PM NAAQS note, the $PM_{2.5}$ mass measurement is a better indicator of visibility impairment during daylight hours when humidities are low. Moreover, the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during daylight hours. Using the 24-hour primary standard as a proxy introduces error and uncertainty in protecting visibility.
2. CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM measurements in various aspects of its monitoring strategy (e.g., Hopke, March 1, 2002; Henderson, April 20, 2005). The PM Panel notes that expanded deployment of continuous $PM_{2.5}$ monitors is consistent with setting a sub-daily standard to protect visibility, especially given that compliance time frames for secondary standards are less rigid than for primary standards.

Thus, the CASAC requests that the sub-daily secondary standard to protect visibility, as recommended both in the PM Staff Paper and by most of the PM Panel, be favorably reconsidered.

NAAQS Process Comments

Morton Lippmann

Background and Credentials

I began my service to CASAC as a Core Consultant in 1980, became a statutory member in 1982, served as Chair from 1983 through 1987, attended CASAC meetings as a member of the SAB Executive Committee from 1987 through 2001, and have served as a member of CASAC's PM and Ozone Panels until the current year.

I wrote a review and commentary entitled "Role of science advisory groups in establishing standards for ambient air pollutants" that was published in *Aerosol Science and Technology* 6:93-114 (1987). Many of the comments and recommendations therein are still relevant today.

Can the Established Process for Setting NAAQS be Restored and Strengthened?

- Of course it can.
- 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.
- Changes in SAB Staff management recently demanded discontinuance of the issuance of a formal 'CASAC closure letter' on Criteria Documents (CDs) and Staff Papers (SPs).
- This was unwise, and has already resulted in CASAC initiatives to offer public comments after EPA's completion of final versions of the latest PM CD and the Administrator's Proposal for PM NAAQS.
- CASAC needs to regain its ability to fulfill the role mandated by the Clean Air Act Amendments of 1977 to review NAAQS criteria, and the mandate of the Environmental Research and Development Demonstration Authorization Act of 1977 for SAB to review Standards.
- CASAC has always issued its closure letters directly to the Administrator without oversight by the SAB Executive Committee. Its independence is therefore compromised by the imposition of SAB Staff management decisions on its process.

Can the Established Process for Setting NAAQS be Restored and Strengthened? (continued)

The parts of the NAAQS setting process that can and should be strengthened are the parts played by NCEA and OAQPS, and CASAC can and should assist these EPA offices in doing so. The long gestation and document preparation times of CDs and SPs for CASAC review account for the long, drawn-out time scales of NAAQS reviews, not the times attributable to CASAC review and preparation of its reports and letters.

An Urgent CASAC Process Need:

The development of a better and more consistent vocabulary. Terminology that needs to be standardized and used consistently includes:

- **sensitive subgroups:** How large and/or how extra-sensitive does a definable group have to be to warrant the setting of a NAAQS specifically designed to protect them against adverse health effects arising from their exposures to ambient air pollutants.
- **adverse health effects:** What is an 'adverse' health effect? For the limited number of Criteria Pollutants, there should be pollutant-specific effects that are defined in advance of the CD preparation. Is there a degree of adversity that triggers the need for protection by the enforcement of a NAAQS?
- **susceptible individuals:** For those relatively few people whose special susceptibility leaves them unprotected by NAAQS designed to protect sensitive subgroups, how can EPA and state and local agencies provide adequate guidance on measures to avoid harmful exposures.

- **adequate margin of safety:** There is a widespread recognition that, for at least some criteria pollutants, i.e., PM, O₃, and Pb, the available literature provides no evidence for the existence population-based threshold concentrations. Thus, there is a need for a new operational definition of a NAAQS that provides an adequate margin of safety. A 'policy' decision is needed on a level of public health risk that is acceptable when a NAAQS is enforced.
- **population based thresholds:** In the absence of evidence for population based thresholds, there is a need for a 'policy' decision on the most prudent course to follow for risk assessment. Is there an alternative to the assumption that a linear or other smoothed curve that fits the best available epidemiologic data should be used? If so, it needs to be made explicitly.
- **acceptable level of population risk:** A 'policy' decision is needed for the ground rules on what constitutes an acceptable level of population risk when the health effects data are consistent with non-threshold population-based linear or curvilinear relationships. For example, is 3 days of life-shortening of a chronically-ill senior citizen due to a peak in 24-hr PM_{2.5}, or the loss of 1 or 2 I.Q. points in a Pb-exposed child, acceptable?

Process Need: More Clarity in the Interface between Science and Policy

CASAC has recognized, and must continue to recognize that there is a clear need for it to provide advice and guidance to the Administrator and the Congress on the science relevant to the setting of NAAQS, and must avoid, to the extent possible, offering advice on policy decisions. The difficulty in drawing such distinctions is evident if one considers my above stated needs for standardization of key elements of the terminology that CASAC confronts when dealing with NAAQS issues. Each of them approaches or may appear to cross the line between science advice and public policy issues. The choices that must be made on defining or clarifying policy relevant to meeting the legislative mandates must be made by the Administrator and/or by Congress through revisions to established Acts, and CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues.

Review of the Process for Setting National Ambient Air Quality Standards

Prepared by the
NAAQS Process Review Workgroup
for the Assistant Administrators of the
Offices of Air and Radiation and
Research and Development
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CONCLUSIONS OF NAAQS PROCESS WORKGROUP

- ___ It is possible to complete the current process for reviewing a NAAQS within the statutory 5-year review cycle. However, the likelihood that the process *will* be completed in that time frame, in the absence of court-imposed schedules, can be increased by making changes that generally create a more policy-relevant focus and a more internally coordinated, consultative approach to each of the process elements.
- NAAQS decisions could be based on more recent science than has historically been available for consideration by adopting changes that provide a continual compilation/evaluation of science, enhance linkages between science and risk/ exposure assessments, facilitate reaching proposed policy decisions as quickly as possible after the completion of those assessments, and expedite provisional assessment of "new" science, when appropriate, during the rulemaking process.

CONCLUSIONS (continued)

- Distinctions between science and policy judgments made by EPA and by CASAC throughout the NAAQS review process can be clarified and made more transparent, in part, by adopting changes that facilitate the preparation and review of a policy assessment document that is based on, but separate from, the science and risk/exposure assessments.
- Changes that enhance the linkages between the preparation of the science assessment and risk/exposure assessment, which in turn would enhance the linkages between CASAC reviews of these two documents, can also help to ensure that more complete, policy-relevant characterizations of uncertainties are incorporated into these assessments.