



'Back to Basics': A Rush to Judgment

On May 9, 2018, then-EPA Administrator Scott Pruitt issued a memorandum, titled "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards".¹ This article provides context for NAAQS review and an analysis of the memorandum.

Section 109 of the U.S. Clean Air Act (CAA) requires the U.S. Environmental Protection Agency (EPA) Administrator to "complete a thorough review" of the National Ambient Air Quality Standards (NAAQS) at five-year intervals. The CAA further requires the Administrator to "appoint an independent scientific review committee" that "shall complete a review" of existing NAAQS and that "shall recommend to the Administrator any new" NAAQS and "revisions of existing criteria and standards as may be appropriate." CAA Section 108 states that the standards "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air." The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

The Five-Year Requirement

EPA has generally failed to meet the CAA requirement for a five-year review cycle for the NAAQS. For the most recent reviews of the primary NAAQS that focus on public health, including carbon monoxide, lead, nitrogen dioxide, ozone, and particulate matter, the review cycle took between 4.0 years to 7.1 years from the initial call for information for the integrated science assessment (ISA) to the publication of the final rule, with an average of 5.9 years. The current review for sulfur oxides is past the proposed rule stage, but not yet finalized, at just over 5 years. However, EPA is generally completing the review process in a timelier manner than in the past.

Based on the time from the consultation on the integrated review plan (IRP) to its final advice on the policy assessment (PA), the duration of CASAC's role in the most recent six NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years. The scientific aspects of these review cycles have been thorough and of high quality, and have resulted in CASAC advice based on the "latest scientific knowledge" required under the CAA. The separation between the ISA, risk and exposure assessment (REA), and PA facilitates separation of science and policy advice by CASAC. CASAC has also been careful to distinguish policy advice from scientific advice.^{13,14}

The most recent review of the carbon monoxide NAAQS was started more than 13 years from the prior review completed in 1994, and it is now over 7 years since the last revision of the carbon monoxide standard in 2011. For the other five criteria pollutants, the amount of time that elapsed from the end of the prior review cycle to the start of the next ranged from 0.5 years to 2.9 years, with an average of 1.6 years. For the five most recent completed primary NAAQS reviews, it has taken EPA between 1.1 to 3.4 years to finalize a rule, with an average of 1.9 years, after CASAC completed its final advice on the most recent policy assessment.

The May 2018 memorandum quotes from CASAC letters from ca. 2006–2008 regarding putative problems with the current review process that are implied to justify speeding up the process.¹ Those letters addressed concerns with the review process prior to its modification in 2006 or during the

Recent History and Components of the NAAQS Review Process

The process for NAAQS review was revised in 2006 based on consultations within EPA, including the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD), with current and former members of CASAC, and with other stakeholders.² The revised process included four major components: planning; integrated science assessment (ISA); risk and exposure assessment (REA); and policy assessment (PA). Separation between these review steps enables differentiation and transparency regarding scientific issues, which are the main focus of the ISA and a major focus of the REA, and policy issues, which is the main focus of the PA.

The ISA reviews, synthesizes, and evaluates policy-relevant science to establish key scientific findings. Such findings include, for example, characterization of physical and chemical processes that lead to ambient air pollutant concentrations, evaluation of air quality monitoring and modeling methods, spatial and temporal variability in ambient concentrations, quantification of background concentrations, quantification of human exposure, dosimetry and mode of action, identification of adverse effects, causal determination between exposure and adverse effects, characterization of populations potentially at increased risk, environmental and ecosystem effects, and interactions with climate change.^{3,4}

The REA is a quantitative analysis of exposure and risk based upon scientific evidence established in the ISA. The REA builds upon the findings of the ISA, such as regarding key adverse effects and populations at increased risk, to provide details regarding input data and modeling methods and results for assessment of exposure and risk.^{5,6} The PA was initially in the form of an advanced notice of proposed rulemaking (ANPR). An April 2007 memorandum modified the process to enable CASAC to review a second draft of the REA and for the REA to be finalized before an ANPR was issued.⁷ In May 2009, then-Administrator Lisa Jackson deleted the ANPR and replaced it with a policy assessment (PA).⁸ The ANPR is a regulatory document that involves input from politically-appointed leadership, whereas the PA is a staff evaluation of the policy implications of the scientific and technical information in the ISA and REA. The PA includes assessment by EPA staff of whether the current standard is adequate and, if not, options for the indicator (pollutant), level, averaging time, and form of possible alternative standards.^{9,10} Taking into consideration the PA, CASAC formulates its advice regarding whether an existing NAAQS should be retained or revised, and whether a new NAAQS is recommended. CASAC logically provides this advice before EPA formulates a proposed rule.

Planning has typically included an integrated review plan (IRP) for the review cycle, and a scope and methods plan (SMP) or similar planning document for the REA.^{11,12} The scientific basis of the review is logically established in the ISA before the REA can be completed. The methodology, input data, and results of the REA have been scientifically reviewed before the PA is finalized.

Brief Primer on CASAC

CASAC is comprised of seven members appointed by the EPA Administrator, referred to as the "chartered CASAC". For each NAAQS review, CASAC has been augmented with additional experts and has been since the 1970s. The augmented panels include multiple experts in each of the many scientific disciplines that pertain to the ISA, REA, and PA. In addition to its mandate under the CAA, CASAC is subject to the Federal Advisory Committee Act (FACA). CASAC meetings must be announced in the Federal Register, the public must be allowed to attend, and CASAC must allow for public comments. Public comments provide an opportunity for stakeholder input to the review process.

For a full review cycle, there is an initial teleconference to convey individual member comments on the IRP, followed by four face-to-face meetings that typically take two days each and focus on: (1) first draft of the ISA and draft of the REA scope and methods plan; (2) second draft of the ISA and first draft of the REA; (3) second draft of the REA and first draft of the PA; and (4) second draft of the PA. Panelists receive a draft document (often hundreds of pages, sometimes over a thousand pages in length) and charge questions from EPA approximately 30 to 60 days prior to a meeting, and submit individual written comments before the meeting.

During the public meeting, the review panel is asked to develop consensus responses to charge questions provided by EPA, but may also provide other advice it deems to be appropriate. After the public meeting, panelists develop a written draft of the responses to charge questions, and may update their individual comments. Although consensus is sought, and often achieved, panelists are always able to convey their individual comments. The panel chair develops a draft letter to the Administrator that conveys the key aspects of CASAC's advice. The draft letter and responses to charge questions are reviewed and deliberated at a teleconference open to the public. The chartered CASAC completes a public "quality review" of each draft report before it is transmitted to the Administrator.

The duration from receipt of a draft EPA report by panelists to the delivery of advice from CASAC to the Administrator is typically 3 to 5 months. EPA staff usually have a good idea of the main points of CASAC's advice at the conclusion of the first public meeting on a particular document, which is typically within 2 months of panel members receiving a draft.

early part of the learning curve for the new process. There were early challenges with the revised process as both EPA staff and CASAC were determining and clarifying the scope and methods relevant to each review step.

A comment from a 2008 letter from CASAC is given without proper context: while it was true at that time that early drafts of ISAs did not exclusively focus on scientific evaluation of the most relevant scientific studies, lessons learned from CASAC's 2008 and other advice have subsequently led to more focused literature reviews and scientific assessments. As another

example, CASAC panels for each criteria pollutant deliberated regarding EPA staff proposals for an updated framework for determination of causality of adverse effects from exposure to air pollutants, leading to improved formulation and clarity of the framework and improved consistency and transparency of its application over time. Thus, the issues raised based on the cited letters from a decade ago are of limited current relevance.

Wait, and Then Hurry Up!

The May 2018 memorandum states that the NAAQS review will be completed by October 2020 for ozone and by December 2020 for particulate matter.¹ Administrator Pruitt took office on February 17, 2017. EPA did not announce the start of the current ozone review until June 26, 2018. Although the current particulate matter review has nominally been underway for more than two years, EPA did not release the first draft of the ISA until October 2018.¹⁵ There are approximately two years from now to the deadlines indicated in the May 2018 memorandum. EPA has never completed a NAAQS review cycle in such a short time.

Can the Review Process be Shortened?

The ISA is critically important to establishing the scientific findings regarding the determination of causality of short- and long-term exposures with regard to adverse effects, and the data and methods relevant to later steps of the review. For each primary NAAQS, two drafts of the ISA were reviewed by CASAC. However, in the case of lead and ozone, a third draft of the ISA was required because CASAC found that the second draft did not adequately address CASAC's prior comments. CASAC has recognized that the ISA, as well as the REA and PA, do not have to be perfect, but must be adequate for their intended purpose, taking into account the CAA mandate that NAAQS be based on "a thorough review" and the "latest scientific knowledge."

The ISA may appropriately contain more information than is later used directly in rulemaking, including scientific questions for which the answer was a null finding. For example, in the previous particulate matter review, a scientific assessment was made that there was insufficient health effects evidence to justify developing a new standard for ultrafine particulate matter (UFP).^{3,9} EPA and CASAC considered UFP in deciding, at that time, not to recommend a standard for UFP. Identification of key uncertainties is also critical to CASAC's mandate to advise the administrator of areas where new science is needed that may be relevant in the next review cycle.

In cases for which there has been limited new information since the last review, the REA either has been omitted, relying instead on the REA from the prior review cycle, had minor updates, or been combined into the PA. CASAC has been amenable to these adjustments to the review process, when appropriate. However, the duration of the review process does not appear to be highly correlated with whether a separate REA is produced. For example, from the initial call for information for the ISA to the publication of the proposed rule, the reviews for which there was not a separate REA took

58 to 66 months. The review for sulfur oxides, with only a single draft of the REA, took 61 months. In contrast, the reviews for carbon monoxide, ozone, and particulate matter, for which there were two drafts of the REA, took 41, 75, and 60 months, respectively.

Combining Multiple Steps into One Step

The May 2018 memo states that EPA "shall consider combining" the ISA, REA, and PA "into a single review."¹ One of the benefits of sequencing these documents is to avoid a problem with an initial draft of one document, such as the ISA, from propagating to later steps in the REA and PA.³ Combining these documents into one review could lead to an inadequately developed scientific basis, a premature risk and exposure assessment, and a poorly supported policy assessment. Furthermore, the sequence of these documents increases transparency regarding science and policy issues.

A single review step would imply that EPA staff working on the REA and PA are presuming the outcome of the ISA before the content of the ISA has stabilized based on CASAC review. Combining these steps would presume that the policy outcome is known before the scientific assessment has been finalized. A rushed combined process would be inherently less transparent.

One of the key reasons why EPA discontinued the use of an advanced notice of proposed rulemaking (ANPR) and replaced it with a policy assessment was because the former was "vulnerable to the introduction of policy options that are not supported by the relevant scientific information," whereas the PA "presents a transparent staff analysis of policy options...to consider prior to rulemaking."⁸ Publication of a PA prior to a proposed rule enables EPA to demonstrate that it has completed a science-based review and fosters the identification and evaluation of science-based regulatory alternatives.

Merely because EPA might proffer a combined assessment for CASAC to review does not mean that CASAC must concur that the combined assessment is adequate. Scientific shortcomings in a combined assessment could lead to CASAC requests for revised drafts. Logistically, there is also the challenge of asking CASAC to compress its review activities into a much shorter time frame. It is debatable whether a CASAC panel could easily digest a combined ISA-REA-PA and deliberate on its advice without additional review and meeting time, while maintaining the level of quality consistent with current practice and the mandate of the CAA.

Sudden Death: Eliminating the PM and Ozone Review Panels

On October 11, 2018, members of the CASAC PM (particulate matter) Review Panel received an email from EPA stating that "your service on the panel has concluded." The PM Review Panel was appointed in 2015 and originally had 26 members. Also on October 11, 2018, candidates for the CASAC Ozone Review Panel were informed that "the Agency will not form a CASAC Ozone Panel." The ozone review panel for the review cycle completed in 2015 had

20 members. There was no prior consultation with members of the PM Review Panel, nor any public indication that elimination of the panels was being considered, nor any public process for providing input related to this issue.

In an October 10, 2018, press release, EPA announced that the chartered seven-member CASAC would conduct the reviews of both the ozone and PM NAAQS simultaneously. Thus, instead of having approximately 20 or more experts chosen for relevant expertise review separate planning, ISA, REA, and PA documents over a period of typically three years, a committee of only seven members will conduct a review in a period that would have to be only about one year, taking into account time for EPA to develop and publish proposed and final rules.

Furthermore, rather than have two mostly non-overlapping groups of experts conduct the reviews, subject to approval by the chartered CASAC, the same group of seven will review these two NAAQS concurrently. For PM in particular, there has been a tremendous amount of new research since the last review, as indicated by the 1,800+-page length of the first draft ISA released just days after the PM Review Panel was disbanded.¹⁵ EPA has argued that the CAA does not require that CASAC be augmented with additional experts. However, it has been clear for the last four decades that a seven member group does not have the breadth and depth of scientific expertise needed for these reviews, and CASAC's charter allows for the formation of panels.

Transforming CASAC from a Scientific to a Stakeholder Committee

Over the decades, CASAC members have been appointed based on their scientific expertise. In contrast, an October 31, 2017, memo from Administrator Scott Pruitt requires that members of EPA federal advisory committees should "reflect prominent participation from state, tribal, and local governments," and that priority should be given to "geographic diversity."¹⁶ There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB).

On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the seven-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

The memorandum states that "no member of an EPA federal advisory committee currently receive EPA grants," but that this "principle should not apply to state, tribal, or local government agency recipients of EPA grants."¹⁶ This is illogical for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not

another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."¹⁷ A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.¹⁸ However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member's work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have a conflict of interest.

The October 31, 2017, memo calls for greater turnover in membership of EPA advisory committees, but fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve.¹⁶ Under this new policy, well-qualified scientists have been "rotated" off of the CASAC, in favor of new members selected for their affiliation or geographic location.

CASAC Advice on Implementation of NAAQS

The CAA states that CASAC shall advise the EPA Administrator regarding "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of NAAQS. However, past administrations have typically not asked CASAC for this advice, nor have EPA staff prepared scientific assessment documents for CASAC review that would be relevant to developing such advice. The May 2018 memorandum indicates that EPA will include a charge question to CASAC seeking such advice.¹

In a June 26, 2014, letter to the EPA Administrator, CASAC outlined how such advice would need to be developed, taking into account that it is illegal to consider cost or technological feasibility when setting a NAAQS.¹³ CASAC stated that it did not want to commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS. CASAC noted that not all implementation effects are adverse; therefore, "any comprehensive assessment would include both adverse and beneficial effects." For example, there are economic benefits from avoided morbidity and premature mortality.

CASAC further advised that "the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review." The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC's mandate. Review of

implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards. Furthermore, EPA should recognize that as a scientific advisory committee, it would be CASAC's responsibility to take a scientific approach to providing advice regarding implementation effects based on valid methods and data, and that such advice cannot be based merely on anecdotes or stakeholder opinions.

CASAC historically relies on EPA staff to prepare draft documents and does not have the resources to commission its own studies. The May 2018 memorandum indirectly acknowledges that CASAC needs to be provided with relevant documents. To clearly separate its advice on implementation versus advice on the standards themselves, an appropriately formulated separate CASAC NAAQS implementation review panel should be provided with a separate draft implementation assessment document. It is likely that there will be a significant learning curve for the both the agency and CASAC in dealing with assessment of implementation issues, which should be recognized in setting schedules. The timing of CASAC advice regarding implementation logically would not be the same as that regarding whether to revise a standard, to avoid conflating implementation issues with the development of advice regarding the setting of NAAQS.

Lack of Transparency about Transparency

The story is not complete without mentioning the proposed rule regarding "transparency" in regulatory science. This proposed rule could have the effect of banning some scientific studies that have been influential in prior NAAQS reviews. As the SAB has pointed out, this proposed rule was not developed based on a transparent process.¹⁹ For example, there was no consultation with the SAB or CASAC, nor were EPA staff scientists or external scientists consulted or offered the opportunity for input. Policies regarding how science is conducted at EPA are usually developed as guidance documents, not as regulations. Although increased transparency is a broadly shared goal in the scientific community, there are legitimate scientific studies for which the underlying data are based on confidential human subject data.

A Way Forward

EPA is a science-based agency with a science-based mission to protect the public health, as mandated by the laws under which EPA must operate. The combined effect of multiple rushed and poorly founded ad hoc initiatives, including the October 31, 2017, and May 8, 2018, memoranda, a proposed rule to ban the use of particular types of scientific studies, the conversion of CASAC to a stakeholder committee, and the summary dismissal of an existing review panel, undermines the application and evaluation of science in the NAAQS review process.

A one-year time frame for NAAQS review by a reconstituted CASAC, for which a highly qualified augmented review panel was dismissed for one pollutant and not formed for another, will create problems that could call into question the quality and adequacy of the review. Although EPA is required to complete

NAAQS reviews in five years, EPA clearly has “gotten away” with longer review cycles. In some cases, EPA has been sued and courts have supervised the timing of the review process. Court approved or ordered completion schedules have taken into account the need for adequate scientific review time. For example, under consent decrees for the recent nitrogen dioxide and sulfur oxides reviews, EPA followed an appropriate process that preserved the integrity of the scientific review. In the current cases for PM and ozone, EPA has wasted a lot of time in getting the reviews underway.

EPA could shorten the length of the review process by reducing the time between the conclusion of the prior review and the start of the next review, and possibly by reducing the time to the final rulemaking after receiving final CASAC advice. EPA could also potentially reduce review time if it is able to commit staff resources to the ISA, REA, and PA to shorten the calendar time, but not the scope and quality, of the development effort for each draft report submitted to CASAC. To maintain the credibility of the process, CASAC should continue to review separate ISA, REA, and PA documents, and complete its advice on the PA

prior to EPA formulating a proposed rule. EPA should abandon the arbitrary constraints imposed on CASAC membership. CASAC should continue to engage additional experts as has been the case for approximately three decades, should reinstate the PM Review Panel, and should form an ozone review panel.

EPA staff in the Office of Research and Development (ORD) and Office of Air and Radiation (OAR) should be lauded for their good faith efforts over the years to shorten the review time for NAAQS, as illustrated by the development and implementation of new processes since 2006. CASAC has generally tried to honor EPA's schedule needs by recognizing that assessment documents must be adequate for their intended purpose but do not need to be perfect. The May 2018 memorandum was not developed based on an open and transparent process. For example, there was no consultation with CASAC. If EPA wants to revise the NAAQS review process, it should do so via an open and transparent process similar to that undertaken in 2006. Such a process would lead to a more accurate understanding of the key needs and challenges of a NAAQS review and perhaps effective ideas for more timely reviews. **em**

H. Christopher Frey, Ph.D., is the Glenn E. Futrell Distinguished University Professor in the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. He served as chair of the U.S. Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee (CASAC) from 2012 to 2015, and has served on CASAC review panels for all six criteria pollutants. He was a member of the CASAC PM Review Panel that was recently disbanded. He recently completed six years of service on the EPA Science Advisory Board (SAB). These are Dr. Frey's personal views. They do not represent any official position of EPA, the CASAC, or the SAB. E-mail: frey@ncsu.edu.

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