A first-hand commentary on the Clean Air Scientific Advisory Committee’s role in the most recent National Ambient Air Quality Standards reviews and recommendations for how future reviews could be improved.
Section 109(d)(1) of the U.S. Clean Air Act requires “…at five-year intervals… the [EPA] Administrator shall complete a thorough review of the criteria published under Section 108 and the national ambient air quality standards…and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate….” Section 109(d)(2)(A) requires the U.S. Environmental Protection Agency (EPA) Administrator to “appoint an independent scientific review committee composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing state air pollution control agencies.”

Section 109(d)(2)(B) provides that this committee “shall complete a review of the criteria…and the national primary and secondary ambient air quality standards…and shall recommend to the Administrator any new…standards and revisions of existing criteria and standards as may be appropriate….” For the past four decades, this independent scientific review committee requirement has been fulfilled by the Clean Air Scientific Advisory Committee (CASAC). The purpose of this article is to describe CASAC’s role in the most recent U.S. National Ambient Air Quality Standards (NAAQS) reviews and provide recommendations for how future reviews could be improved.

**Recent CASAC Activity**

Over the past three years, the CASAC has been involved with reviewing the particulate matter (PM) and ozone NAAQS. EPA’s NAAQS review process involves three phases: planning, assessment, and rulemaking. During the planning phase, EPA develops the Integrated Review Plan (IRP), which includes timelines and key policy-relevant issues and scientific questions. The CASAC develops a letter to the EPA Administrator with individual CASAC comments.

During the assessment phase, EPA usually develops three documents: (1) Integrated Science Assessment (ISA), which includes an evaluation and synthesis of most policy-relevant studies; (2) Risk and Exposure Assessment (REA), which is a quantitative assessment focused on key results, observations, and uncertainties; and (3) Policy Assessment (PA), which includes staff analysis of policy options based on integration and interpretation of information in the ISA and REA. CASAC is asked to review draft versions of these documents and respond to a set of charge questions assembled by EPA and used to guide the CASAC review of the documents. The CASAC develops a letter to the EPA Administrator that includes consensus response to charge questions and individual CASAC comments. CASAC does not review the final versions of these documents. Also, CASAC is not involved with the rulemaking phase.

Traditionally, the CASAC works with a special panel of experts to review and evaluate the IRP, ISA, REA, and PA. This CASAC expert review panel typically consists of 20–30 members and works directly with the CASAC to help develop responses to EPA charge questions. However, many of the traditional CASAC roles were transformed with the EPA Administrator’s May 9, 2018 “Back to Basics” memo, which directed EPA to expedite the PM and ozone NAAQS reviews (targeting completion by the end of 2020), identified ways to streamline the review process (e.g., avoiding multiple drafts of documents), and identified a standardized set of charge questions for CASAC. As a result, the PM review panel was dissolved, and the ozone review panel was never formed. This placed the full responsibility of the CASAC review on the shoulders of the seven-member CASAC. The current CASAC members are listed in Table 1. Dr. Kendall did not participate in the PM review based on his timing of joining the CASAC, but he did participate in the ozone review.

**PM NAAQS Review**

EPA’s draft PM ISA was released in October 2018. CASAC met on December 12–13, 2018, and March 28, 2019, to discuss the draft PM ISA. CASAC submitted a letter on the draft PM ISA to the EPA Administrator on April 11, 2019. The letter stated: “Overall, the CASAC finds that the Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter (PM). The CASAC recommends that the following fundamental limitations be remedied in a second draft of the ISA for CASAC review:

- Lack of comprehensive, systematic review…
- Inadequate evidence for altered causal determinations…
- Clearer discussion of causality and causal biological mechanisms and pathways… “

For the causality determinations, “The CASAC finds that the Draft ISA does not present adequate evidence to conclude that there is likely to be a causal association between long-term PM$_{2.5}$ exposure and nervous system effects; between long-term UFP [ultrafine particles] exposure and nervous system effects; or between long-term PM$_{2.5}$ exposure and cancer.” Also, CASAC made the following two process recommendations:

1. The CASAC recommends development of a Second Draft ISA for CASAC review.
2. The CASAC recommends that the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise). The panel should be appointed in time to review the Second Draft ISA.

On September 13, 2019, EPA announced the selection of a pool of non-member subject matter experts (consultants) to support the CASAC’s review of the PM and ozone NAAQS.
These non-member consultants were allowed to respond formally in writing to written questions from the CASAC members; however, verbal discussions with them were not allowed.

EPA’s final PM ISA was released in December 2019. The final PM ISA revised the causality determination for long-term ultrafine particle exposure and nervous system effects from “likely to be a causal” to “suggestive of, but not sufficient to infer a causal relationship” and added additional text to the Preface of the PM ISA, as well as text in the health effects chapters to clarify the discussion of biological plausibility (the presence of a potential biological mechanism) and its role in forming causality determinations.

EPA’s draft PM PA was released in September 2019. The EPA staff preliminary conclusion was that the current primary annual PM2.5 standard was not adequate and should be lowered, but the current 24-hr PM2.5 standard, PM10 standard, and secondary PM standards were adequate and should be retained. CASAC met on October 22, 2019, and October 24–25, 2019, to discuss the draft PM PA. CASAC submitted a letter on the draft PM PA to the EPA Administrator on December 16, 2019.

EPA’s draft PM PA was released in September 2019. The letter stated: “…some CASAC members conclude that the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 PM2.5 annual standard. Other members of CASAC conclude that the weight of the evidence…does reasonably call into question the adequacy of the 2012 annual PM2.5 [NAAQS] to protect public health with an adequate margin of safety. The CASAC also finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current 24-hr PM2.5 standard, PM10 standard, or secondary PM standards and concurs that they should be retained.”

In addition, “The CASAC recommends that the final PM PA provide quantitative uncertainty and sensitivity analyses to provide a clearer technical and scientific basis for data interpretation and policy making.” CASAC concluded with “The CASAC recommends that it be provided an opportunity to review a revised draft of the PM PA based on the final PM ISA.”

EPA’s final PM PA was released in January 2020. The EPA staff final conclusions as to the adequacy of the PM standards were consistent with their preliminary conclusions.

Table 2 is a summary of the EPA preliminary/final conclusions and the CASAC conclusions on the adequacy of the current PM standards.

**Ozone NAAQS Review**

EPA’s draft ozone ISA was released in September 2019. CASAC met on December 3–6, 2019, and February 11–12, 2020, to discuss the draft ozone ISA. CASAC submitted a letter on the draft ozone ISA to the EPA Administrator on
February 19, 2020. The letter stated, “The CASAC recommends that the following key points be addressed in the final ozone ISA:

- Critically review, synthesize, and discuss available scientific evidence on how changes in public health effects depend on changes in ambient ozone exposures. This is a crucial scientific topic for informing the ozone PA and should be thoroughly addressed in the ozone ISA.
- Clarify criteria used to select, evaluate, weight, and summarize studies; provide details of how the criteria were applied to individual studies and what the results were; and explain how key conclusions were derived from the results.
- Clarify the meaning and derivation of stated key causal conclusions. Causal determination judgments stated in the draft ozone ISA are ambiguous, and sometimes appear subjective and arbitrary.”

In addition, the letter stated, “On overarching process issues, the CASAC strongly recommends that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels, while also keeping the option of obtaining written responses from external experts to specific questions.” EPA’s final ozone ISA was released in April 2020.

EPA’s draft ozone PA was released in October 2019. The EPA staff preliminary conclusion was that the current primary and secondary ozone standards were adequate and should be retained. CASAC met on December 3–6, 2019, and February 11–12, 2020, to discuss the draft ozone PA. CASAC submitted a letter on the draft ozone PA to the EPA Administrator on February 19, 2020. The letter stated, “… some CASAC members conclude that the draft ozone PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current primary ozone standard. Other members of the CASAC agree with the previous CASAC’s findings and recommendations in their review of the 2014

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>Position</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Louis Anthony Cox, Jr.</td>
<td>Cox Associates, Denver, CO</td>
<td>President</td>
<td>2017</td>
</tr>
<tr>
<td>(CASAC Chair)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. James Boylan</td>
<td>Georgia Department of Natural Resources, Atlanta, GA</td>
<td>Planning &amp; Support Program Manager</td>
<td>2017</td>
</tr>
<tr>
<td>Dr. Mark Frampton</td>
<td>University of Rochester Medical Center, Rochester, NY</td>
<td>Professor Emeritus</td>
<td>2018</td>
</tr>
<tr>
<td>Dr. Sabine Lange</td>
<td>Texas Commission on Environmental Quality, Austin, TX</td>
<td>Toxicology Section Manager</td>
<td>2018</td>
</tr>
<tr>
<td>Dr. Corey Masuca</td>
<td>Jefferson County Department of Health, Birmingham, AL</td>
<td>Principal Air Pollution Control Engineer</td>
<td>2018</td>
</tr>
<tr>
<td>Dr. Steven C. Packham</td>
<td>Utah Department of Environmental Quality, Salt Lake City, UT</td>
<td>Toxicologist</td>
<td>2018</td>
</tr>
<tr>
<td>Dr. Ronald Kendall</td>
<td>Texas Tech University, Lubbock, TX</td>
<td>Professor of Environmental Toxicology</td>
<td>2019</td>
</tr>
</tbody>
</table>

Table 1. Current CASAC members, affiliation, position, and year appointed to CASAC.
was released in May 2020. The EPA’s final ozone PA

\[\text{Given an opportunity to review a second draft of the ozone determination framework.} \]

\[\text{CASAC concluded with the conclusions and CASAC conclusions on the adequacy of the current ozone standards.} \]

Table 3 is a summary of the EPA preliminary/final conclusions as to the adequacy of the ozone standards were consistent with their preliminary conclusions. Table 3 is a summary of the EPA preliminary/final conclusions and CASAC conclusions on the adequacy of the current ozone standards.

<table>
<thead>
<tr>
<th>PM Standard</th>
<th>EPA Preliminary/Final Conclusion that the Current Standard is Adequate</th>
<th>CASAC Conclusion that the Current Standard is Adequate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Ozone</td>
<td>Yes</td>
<td>Yes (6), No (1)</td>
</tr>
<tr>
<td>Secondary Ozone</td>
<td>Yes</td>
<td>Yes (7)</td>
</tr>
</tbody>
</table>

*Numbers in parenthesis represent the number of CASAC members drawing each conclusion.

Second draft ozone PA. In that review, the previous CASAC opined that a primary standard set at 70 ppb [parts per billion] may not be protective of public health with an adequate margin of safety. The CASAC also finds, in agreement with the EPA, that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standard and concurs that it should be retained.”

In addition, the letter stated, “On overarching process issues, the CASAC strongly recommends that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels, while also keeping the option of obtaining written responses from external experts to specific questions. The CASAC strongly recommends that the EPA work with experts in causal analysis, biological causation, management science, decision analysis, and risk analysis to improve the causal determination framework.” CASAC concluded with the following statement: “The CASAC recommends that it be given an opportunity to review a second draft of the ozone PA (with an updated Risk and Exposure Assessment) after the final ISA for ozone is released.”

EPA’s final ozone PA* was released in May 2020. The EPA staff final conclusions as to the adequacy of the ozone standards were consistent with their preliminary conclusions. Table 3 is a summary of the EPA preliminary/final conclusions and CASAC conclusions on the adequacy of the current ozone standards.

**Personal Perspective**

Reviewing two complicated and controversial NAAQS simultaneously is a difficult and time-consuming task. Just the time alone to read the draft documents can be substantial: PM ISA (1,879 pages), PM PA (457 pages), ozone ISA (1,411 pages), and ozone PA (926 pages). This task was made even more difficult by not having the assistance of the traditional review panels and the EPA Administrator’s decision to complete both reviews by the end of 2020. While the EPA is required by the Clean Air Act to complete NAAQS reviews for each criteria pollutant every five years, they have historically failed to meet that statutory deadline (e.g., 1997/2008/2015 for ozone, 1997/2006/2012 for PM). Due to the time required to perform a comprehensive NAAQS review, I would support changing the five-year interval to an eight-year interval.

I feel strongly that EPA should bring back the traditional review panels for future NAAQS reviews. This panel would provide the seven-member CASAC with additional insight and expertise to allow for a more thorough and in-depth review of the relevant science and policy documents. While the pool of non-member consultants did provide additional insight and useful information for the PM and ozone reviews, it was not an adequate replacement for the traditional review panel. My experience serving on the CASAC sulfur (SO2) review panel (2014–2018) allows me to directly compare the traditional review panel approach to the new non-member consultants approach. While on the SO2 review panel, I learned the importance and value of having multiple nationally recognized experts with differing backgrounds and opinions thoroughly reviewing each document. Although EPA made available non-member consultants to formally respond in writing to written questions from the CASAC members, it was not the same as the traditional review panel which directly participated in the deliberations and drafting of consensus comments.

With a CASAC of only seven people, all areas of science were not adequately represented (e.g., epidemiology) or only represented by one person. For example, I was the only person on CASAC that specialized in photochemical modeling for PM and ozone. With the traditional review panel, there are typically multiple people with similar areas of expertise that can meet in small groups of 3–4 people to discuss and debate scientific approaches and interpretation of results. Under the current review scenario, there were certain topics where only one CASAC member was a subject matter expert leading to little debate and discussion on alternative approaches and interpretation of results. Hence, that one CASAC member’s comments on those subjects became the default consensus CASAC comments. For the more controversial topics, I would have liked to have seen additional subject matter experts with differing opinions (e.g., the disbanded PM review panel) directly participate in the discussions with the CASAC rather than simply providing their written and verbal comments via the public comment forum. This would allow for a more comprehensive examination of controversial topics.
It was unfortunate that EPA did not follow the CASAC recommendations to provide second draft versions of the PM ISA, PM PA, and ozone PA for CASAC to review. Since the EPA Administrator set a deadline for these reviews to be completed by December 2020, second draft versions of these documents were not made available for CASAC review and many of the CASAC comments were not adequately addressed in the final versions of these documents. If EPA had been given adequate time to fully address the CASAC comments and provided CASAC with second draft versions of these documents, some CASAC members may have changed their determination as to the adequacy of the standards.

To further streamline the PM and ozone review processes, EPA developed the draft PA prior to finalizing the ISA and incorporated the REA into the PA. The purpose of the PA is to bridge the gap between EPA’s scientific assessments and the judgment required by the EPA Administrator when determining whether to retain or revise the NAAQS. Therefore, the ISA should be finalized prior to developing the REA and the REA should be a stand-alone document that is reviewed by CASAC and the public prior to the release of the PA. This will allow scientific review of the risk and exposure metrics prior to developing policy recommendations.

In the future, EPA should consider spacing out the PM and ozone reviews, starting the review process sooner to allow for multiple drafts of the ISA and PA documents, providing the REA as a stand-alone document prior to release of the PA, and bringing back the traditional review panels.

References
2. Integrated Science Assessment for Particulate Matter (External Review Draft); EPA/600/R-18/179; U.S. Environmental Protection Agency, October 2018.

45th Annual A&WMA Information Exchange
Virtual Conference • December 9-10, 2020

Get the latest information on research and regulatory issues directly from the experts!

Join A&WMA at one of the best kept secrets in the industry for information exchange, discussion, and solutions. This year’s virtual program will include presentations from U.S. EPA experts on power sector rules, air sensors, MM2A, Risk and Technology Review (RTR), NAAQS, New Source Review, and more.

Additional speakers from industry, NGOs, agencies and academia will share their expertise and the latest solutions for maintaining compliance and reducing environmental impacts.

Virtual conference access includes livestream sessions, recordings, and slides through March 31, 2021.

Register now at www.awma.org/infoexchange.