

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Chartered Clean Air Scientific Advisory Committee (CASAC)
Public Meeting on Particulate Matter and Ozone
December 3-6, 2019**

Date and Time: Tuesday, December 3, 2019 - Friday, December 6, 2019

Location: Embassy Suites by Hilton Raleigh Durham Research Triangle, 201 Harrison Oaks Boulevard, Cary, North Carolina, 27513; telephone; and live audio webcast.

Purpose: To discuss CASAC's Draft Report on EPA's Policy Assessment for Particulate Matter,¹ to peer review EPA's *Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019)*,² and to peer review EPA's *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)*³

Participants: Chartered CASAC Members (also see roster⁴)

Dr. Tony Cox, Chair
Dr. James Boylan
Dr. Mark Frampton
Dr. Ronald Kendall
Dr. Sabine Lange
Dr. Corey Masuca
Dr. Steven Packham

Mr. Aaron Yeow, Designated Federal Officer (DFO)
Mr. Tom Brennan, EPA Science Advisory Board Staff Office

Dr. John Vandenberg, EPA Center for Public Health and Environmental Assessment (CPHEA)
Dr. Tom Luben, EPA CPHEA
Dr. Meredith Lassiter, EPA CPHEA
Dr. Erika Sasser, EPA Office of Air Quality Planning and Standards (OAQPS)
Dr. Deirdre Murphy, EPA OAQPS
Dr. Stephen Graham, EPA OAQPS

Other Attendees (See Attachment A)

Tuesday, December 3, 2019

Convene Meeting and Welcome

Mr. Aaron Yeow, DFO, opened the meeting. He noted that, as required under the Federal Advisory Committee Act (FACA), CASAC meetings are held in public, with advance notice given in the Federal Register.⁵ He stated that FACA required that public meetings allow for public comment and that there were public comment periods noted on the agenda⁶ where members of the public registered in advance

to make public comments. He also noted that there were clarifying public comment periods on the agenda where members of the public could request an opportunity to make clarifying comments providing new additional information to the CASAC. He stated that the meeting minutes would be made publicly available after the meeting. He stated that the SAB Staff Office determined that there were no financial conflicts of interest or appearance of a loss of impartiality for any of the CASAC members.

He turned the meeting over to Mr. Tom Brennan, Director of the EPA Science Advisory Board Staff Office, who welcomed everyone and thanked the members of the public for their participation, the CASAC members for all their public service, and the EPA staff for their efforts in developing the review documents. He asked the CASAC members to introduce themselves and then turned the meeting over to Dr. Tony Cox, Chair of the CASAC.

Dr. Tony Cox indicated that one of the key goals was to provide high quality and useful feedback to the EPA. He stated that another objective was to hear from the public, which would be next. The CASAC would then discuss any revisions needed for the Draft CASAC PM PA Report and then finalize the report.

Public Comments

Mr. Yeow indicated that they would proceed in the order presented in the List of Registered Public Speakers.⁷ He noted several ground rules for the public comment period: comments would be limited to 5 minutes; comments should be focused on the documents under review; comments would have the most impact if they provide specific scientific or technical information or analysis for CASAC to consider or if it relates to the clarity or accuracy of the technical information; and that commenters should remain professional and civil, refraining from any personal attacks.

Gretchen Goldman, Union of Concerned Scientists, stated that the review process was broken (dismissal of PM Panel, expedited timeline, comingling of science and policy, etc.) She urged the CASAC to follow the advice of the Independent PM Review Panel and summarized their advice. She stated that EPA's causal framework was well-vetted and endorsed by the scientific community. Dr. Cox stated that a method is scientifically well-vetted when predictive validity has been empirically established and its performance characterized. He asked her whether the performance and predictive accuracy of causality determinations have been characterized with this type of quantitative scientific vetting. She stated that the weigh-of-evidence (WOE) approach used by EPA is consistent with what the National Academies had said, consistent with Bradford-Hill, and has gone through 138 experts. He stated that in 2014, the National Research Council concluded that "The committee views weight-of-evidence analysis as a judgment-based process for evaluating the strength of evidence to infer causation. However, it found that the phrase as used in practice has become too vague and is of little scientific use." He added that a 2015 review of WoE by Linkov et al. states that "The question of whether WoE is a legitimate tool that should continue to be developed and formalized or an obsolete concept that should be disregarded and replaced by something else altogether is thus a subject of significant interest," emphasizing "the fundamental necessity of validating test methods as well as improving overall flexibility, transparency, consistency, reproducibility and objectivity of WoE" and stating that "Qualitative approaches, as they apply to WoE, will likely lack the transparency and objectivity to be accepted by regulatory science communities. This lack of clarity and systematic methodology similarly reflects the findings mentioned as justification for discarding WoE studies and declaring them to be of 'little scientific use.'" Dr. Cox asked her if, despite such limitations, she still considered EPA's WOE approach to be well-vetted and endorsed by the scientific community. She stated that she does and that the context they are looking at these issues is the Clean Air Act and what provides an adequate margin of safety. He asked her about

her statement that the appointment of consultants being far too late to provide any substantive benefits. He asked whether, in her view, the CASAC asking questions and receiving useful responses were not substantial benefits. She stated that it was not sufficient for what was needed here, that there were issues with the process of how they were appointed, that they were not able to weigh in on the PM ISA, and it was not the same as the robust scientific discussion that would have occurred if a panel were at the table. He asked her if there were no substantive benefits to having the pool of consultants. She responded that there were limited benefits and that it was better than nothing, but could not be considered a replacement for a panel.

Julie Goodman, Gradient, stated that while most CASAC members concluded the new scientific evidence and data do not call into question the adequacy of the PM_{2.5} standard, other members concluded this was not the case based primarily on epidemiology studies reporting statistically significant associations in areas with mean concentrations below the current standard. She stated that conclusions regarding these specific epidemiology studies are unwarranted. She focused on several issues that could be included in the CASAC report: the use of mean exposures from epidemiology studies in the risk assessment, pseudo-design values likely overestimating the extent to which study areas met the current standards, and evaluating hypothetical air quality scenarios with unvalidated approaches.

Lianne Sheppard, University of Washington, presented her oral statement⁸ and stated that she wanted to alert the CASAC that much of the advice in the Draft CASAC PM PA Report was not fit for purpose, actionable, balanced, or based on well-vetted credible scientific principles and urged them to substantially revise the draft report. She stated that the causal inference concepts being advocated in the draft report are technically unsound. Dr. Cox asked her whether it was her opinion that residual confounding was equally likely to create false positives and false negatives. She indicated that effects of confounding could go in either direction. He asked her whether the eight key studies in Appendix C of the Draft PM PA addressed confounding as thoroughly as possible. She stated that it was her opinion that the investigators did the best job they could in addressing confounders. He asked whether they specifically addressed confounding by temperature and daily high and low temperatures as thoroughly as possible. She stated that these were cohort studies, which look at spatial contrast based on where people live and that it doesn't make sense to incorporate temperature in those type of studies. She indicated it does make sense to incorporate temperature in time-series studies, but not cohort studies. He asked whether this was thorough. She stated that there is always room for additional scientific investigation but she did not think that was a reason to discount the eight case studies. She stated that it was the evidence they had and it was high-quality evidence that should be trusted. If additional scientific studies were performed in the future that suggests concerns about temperature were valid, she is sure EPA would take that into consideration. He asked her regarding a statement in her written comments⁹ that "Pearl's book (2009) does not address causal inference from observational data, which is the type of data being considered in the risk assessment." He stated that Pearl's work does address causal inference from observational data explicitly, and that this is its main emphasis, quoting from Pearl's work to support this point. She replied that if her understanding were incorrect, she would need to look into it further.

Sumita Khatri, American Lung Association (ALA), presented her oral statement,¹⁰ which focused on ALA's opposition to the process EPA adopted in this review and their urging EPA to strengthen the annual PM_{2.5} to 8 µg/m³ and 24-hour standard to 25 µg/m³.

James Enstrom, UCLA (retired) and Scientific Integrity Institute, stated that he was the only independent investigator who analyzed the American Cancer Society (ACS) data that underlies Pope et

al. (1995), which was the primary study that established the 1997 PM_{2.5} NAAQS and strongly supported the Draft CASAC PM PA Report and the way causality was handled. He stated that EPA's Scientific Integrity process and scientific journal peer review process were broken.

John Bachmann, Environmental Protection Network, stated that the current NAAQS review process is fatally flawed, that the Draft CASAC PM PA Report has an emphasis on the use of causal inference methods that are either not properly vetted or do not yet exist over the use of a large body of epidemiology studies as supporting information that do exist. He stated that the split opinion of the 6 members of CASAC who reviewed the PM PA was weak compared to the consensus advice of the 20-member Independent PM Review Panel. He stated that the Draft CASAC PM PA Report is evidence that the understaffed and divided CASAC lacks the depth, breadth, and diversity of expertise and experience needed to ensure the quality and credibility of the NAAQS review process.

Thom Golab, American Council on Science and Health (ACSH), presented his oral statement,¹¹ which focused on stating that the Proceedings of the National Academy of Sciences (PNAS) study on the health impacts caused by air pollution was riddled with errors and that an Imperial College study estimated one-third fewer deaths than the PNAS study and a recent JAMA Network study showed even fewer deaths. He stated that the Draft PM PA has selection bias and cherry-picking by not including the work of ACSH scientists, Dr. James Enstrom and Dr. John Dunn.

Gary Ewart, American Thoracic Society (ATS), stated that the ATS continues to be concerned that the quality and integrity of the CASAC review process has been harmed by the dismissal of the CASAC PM Review Panel. He stated that EPA's selection of a pool of consultants was insufficient to make up for the loss of expertise needed to complete a thorough and well-informed CASAC NAAQS review. He stated that they were also concerned with the overlapping policy and science documents in both the PM and Ozone NAAQS reviews, that the process was rushed and reduced the opportunity for public input. He made three specific points regarding the Draft PM PA: that the current annual PM_{2.5} standard of 12 µg/m³ is not protective and that CASAC should recommend a more protective standard of 8 µg/m³; that the current 24-hour PM_{2.5} standard of 35 µg/m³ is not protective and CASAC should consider recommending a protective 24-hour PM_{2.5} standard of 25 µg/m³; and that the evidence does not support the existence of a threshold for health effects from PM exposure. Dr. Cox asked Mr. Ewart whether measurement error was adequately modeled in the Di et al. study. Mr. Ewart indicated that he did not have the expertise to answer that question.

Steve Milloy, junkscience.com, commended the CASAC for condemning the Draft PM PA and stated that the epidemiology used by the EPA is not science, that there were no animal toxicology studies demonstrating mortality from PM exposure, that there were no clinical human exposure studies demonstrating health effects or mortality from PM exposure, and that there were no real world examples where PM has killed anyone.

Dan Greenbaum, Health Effects Institute, presented his oral statement,¹² which focused on the current state of causality discussion in the ISA, the PA, and Draft CASAC PM PA Report; the discussion at the CASAC October 2019 meeting (and Draft CASAC PM PA Report) of temperature as a potential confounder of air pollution and health relationships; and on the initial results of HEI-funded studies of low levels of exposures to PM and ozone. He stated that the application of causal inference modeling to air pollution analyses was still at a very early stage and comes with its own levels of assumptions and uncertainties. He applauded CASAC's desire to move toward better causality determinations but hoped that CASAC would understand that the existing process does provide useful scientific information and conclusions. He stated that although daily temperature is a potentially important confounder in short-

term studies, it is unlikely to be of significance in the cohort studies which constitute 5 of the 8 key studies in the Draft PM PA. He indicated that initial results from HEI-funded studies reported statistically significant associations of mortality with PM_{2.5} at levels below the current NAAQS. Dr. Cox indicated that he had questions for Mr. Greenbaum, but wanted to let the other public speakers present first, and then would come back to him for questions.

John Dale Dunn, Heartland Institute of Chicago, presented his oral statement,¹³ which focused on the Bradford-Hill rules for proof of causation and that EPA small particles research fails to properly show reliable exposures or biological plausibility, and that reported associations are too weak to be proof of causation.

Daren Bakst, The Heritage Foundation, presented his oral statement,¹⁴ which focused on two main points: that the Draft PM PA should properly consider “null” studies and that the Draft PM PA should only use studies in which there was proper access to underlying data and models.

Rob McConnell, University of Southern California, presented his oral statement,¹⁵ which focused on CASAC’s criticism of epidemiological studies in the Draft PM PA despite having no epidemiologists on the committee, that analyses in the studies in the PM PA were conducted using well-established methods and showed that effects were robust to potential confounding and it is unlikely that weather would explain the effects. He stated that use of a “manipulative causality” framework is still premature.

Chris Frey, North Carolina State University, stated that the existing causality framework has been reviewed by CASAC over the period of more than a decade and evaluated by at least 74 experts over multiple panels and NAAQS review cycles. He stated that the current CASAC does not have the depth, breath, or diversity of expertise and experience for this review. He stated that the CASAC should defer to the Independent PM Review Panel, which has the right depth, breath, and diversity of expertise and perspectives to advise on all of the relevant issues. Dr. Cox asked whether it was the case that there were substantial uncertainties about the levels of individual exposures, specifically for individuals who responded with health effects. Dr. Frey indicated that he noticed a theme in the CASAC comments regarding estimated vs. actual exposures and stated that there was no such thing as actual exposures in these kinds of studies. He noted that one way to look at it is whether the models do a good job of looking at spatial gradients and temporal trends and he thought the models did a reasonable job. Dr. Cox asked whether the models did a reasonable job of predicting spatially-averaged concentrations. Dr. Frey indicated that he did not remember the exact spatial resolution, but that he recalled it was a relatively high resolution and that it would be averaged over a relatively small grid size. Dr. Cox indicated that the resolution was one square kilometer and agreed that was an improvement, however, the models had not been validated as providing accurate estimates for individual exposures. Dr. Cox asked if one divided the population within that square kilometer into those who responded with health effects and those who did not, was it likely that those who responded would have had a higher average concentration than those who did not, even though they were in the same square kilometer. Dr. Frey indicated other sources of variability would have to be looked at more carefully before he could give a clear answer.

Dr. Cox thanked all of the public speakers for providing comments and indicated that the CASAC takes all of the comments into consideration. Dr. Cox returned to asking Dan Greenbaum questions regarding his comments. Dr. Cox asked whether Mr. Greenbaum’s statement that the current causality framework provides useful scientific information and conclusions meant that they have been empirically tested and validated by comparing their testable predictions to data. Mr. Greenbaum indicated that he was referring to the process that the National Research Council called evidence integration, that there was a way to infer causality from that without going to purely statistical tests. Dr. Cox asked whether HEI had any

published analyses showing that the existing causal determination framework provided positive value of information (VOI). Mr. Greenbaum said he would need to look into that.

Discussion of the Draft CASAM PM PA Report

Chapter 2

The CASAC agreed to editing line 9 on page 9 from “uncertain” to “certain.” Mr. Yeow indicated that any typos or grammatical errors could be emailed to him and Dr. Cox and that there was not a need to discuss that during the meeting, saving the time in the meeting for substantive deliberations.

Chapter 4

The CASAC did not have any changes to the consensus response to Chapter 4.

Chapter 5

Dr. Cox indicated that he would add a reference or two for where EPA could find additional information on climate issues.

Chapter 3

Dr. Cox asked if they wanted to keep Figure 1. Reflecting on the public comments, Dr. Cox indicated that Figure 1 may not shed as much light as they intended and stated it might be better just to state the key point and lose the example. Dr. Frampton agreed. The CASAC agreed to delete line 17 on page 16 through line 4 of page 17 and Dr. Lange could add it to her individual comments.

Chapter 1

Dr. Frampton indicated that much of the response to the Chapter 1 charge question was not about Chapter 1 of the PM PA, dealing with issues discussed in the Chapter 3 consensus response and issues with the causality framework. He did not find any issues with Chapter 1 of the Draft PM PA, but had issues with the consensus response in the Draft CASAC PM PA Report. Dr. Cox stated that if there were issues that are adequately covered in the consensus responses to the other charge questions, he would be happy to take that material out. He stated that he found three overarching issues raised in Chapter 1 of the Draft PM PA and he wanted to make sure that comments on those were in the consensus response. Dr. Frampton indicated that he had issues with item (d) on lines 27-29 of page 1. He did not agree with the term “sound science” and did not agree with the reexamination of the causality framework.

Chapter 3 (cont'd.)

Following a lunch break, Dr. Cox asked if there were any additional comments on Chapter 3. Dr. Masuca requested more clarity regarding Major Point 3 on page 17, line 23. The CASAC agreed to add a clarifying statement referring back to CASAC’s comments on the pseudo-design values on page 12. For Appendix A, Dr. Cox agreed to add introductory text stating the issue and what EPA requested.

Chapter 1 (cont'd.)

Dr. Boylan stated that he thought that it was inappropriate for the CASAC to base their final recommendations on first draft documents (ISA, risk assessment, and PA). Dr. Boylan stated that at the October 24-25, 2019, meeting, he initially found that the annual PM_{2.5} standard was not adequate based on the extensive weight of the evidence. After the deliberations, he went back to further review the PA and risk assessment in more detail, and changed his position. He stated that additional analyses would be necessary in order to recommend a revision to the standard. He indicated that it was critical that the ISA be finalized and that a 2nd Draft PA with an updated risk assessment be released for CASAC review prior to the release of a Final PA.

Dr. Frampton asked Dr. Boylan what specifically changed Dr. Boylan's opinion. Dr. Boylan stated that quantitative uncertainty analyses and sensitivity analyses could be performed and have not been performed, confounders could be accounted for, and statistical significance of the results at the different levels could be determined. He stated that these are things that he thought EPA could address and if they did, he would feel much more comfortable with the risk assessment.

The CASAC agreed with recommending that it be provided another opportunity to review a revised draft of the PA based on the final ISA.

The CASAC agreed with striking lines 14-16 of page 1 due to accuracy, with removing point d on lines 27-29 on page 1, and moving the first paragraph on page 1 to a new section for overarching recommendations. The CASAC also agreed to changing removing everything under point (1) on lines 35-43 on page 1 and lines 1-2 on page 2 except for point iii under (1) a. They also agreed to revising point b under (2) to "Better characterize C-R functions for pulmonary inflammation and other physiological responses." The CASAC agreed to revising point (4) on line 24 on page 2 to "Distinguish between average and individual exposures throughout the PM PA;" and to delete everything from line 29 on page 2 through line 37 on page 8.

Discussion of Letter to the Administrator

The CASAC agreed to change "most CASAC members" to "some CASAC members" on line 43 of the first page of the letter, to be consistent with the language in the rest of the report. The CASAC agreed to add the overarching recommendation to the end of the letter.

Additional Clarifying Comments on the Draft CASAC PM PA Report

Gretchen Goldman, Union of Concerned Scientists, stated that CASAC's summary letter should include all of the context by which the advice is given – lack of expertise to do the review, time pressure, limited access to revised drafts.

Disposition of the Draft CASAC PM PA Report

The CASAC members approved the report based on the revisions discussed during the meeting.

The meeting was recessed at 3:45 pm.

Wednesday, December 4, 2019

Public Comments on the Ozone ISA

Gretchen Goldman, Union of Concerned Scientists, stated that CASAC should refuse to comply with the unreasonable task and timeline imposed on them for the Ozone NAAQS process. She indicated that the review was happening at lightning pace and blurring the lines between science and policy by reviewing the ISA and PA during the same meeting. She stated that CASAC did not have the expertise to conduct the review and that the pool of consultants was a poor substitute for an independent panel and did not fill the gaps in the breadth, depth, and diversity of expertise. She urged CASAC to ask to review a 2nd Draft ISA.

Julie Goodman, Gradient, presented an oral statement¹⁶ which focused on: limited study quality information, systematic review and causal determination framework needing to be updated, evidence for respiratory effects not supporting EPA's conclusion, and evidence for metabolic effects not supporting EPA's conclusion. She stated that taken together, the currently available science does not provide evidence that supports health effects at ozone concentrations below the current primary standard. Chris Frey, North Carolina State University, presented an oral statement¹⁷ and stated that he was providing the comments on behalf of himself and 17 other members of the former CASAC Ozone Panel and referred to their written comments.¹⁸ He stated that the NAAQS review process changes are harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body. He stated that an ozone panel should be formed and that the current 7-member CASAC does not have the breadth, depth, or diversity of expertise and experience needed for the ozone review.

David G. Hill, American Lung Association, presented an oral statement¹⁹ focused on expressing their objections to the NAAQS review process changes, agreeing with many of the conclusions of health effects from ozone, and urging EPA to review and reconsider some determinations. He stated that the ISA shows growing evidence that the current standard of 70 ppb is not protective. He pointed to the example of outdoor workers, which include healthy young adults, who, in chamber studies, experienced harm at ozone levels of 60 ppb, well below the current standard.

Gary Ewart, American Thoracic Society (ATS), stated that although EPA has a statutory obligation to review the NAAQS every five years, the EPA has been highly selective in which statutory obligation to adhere to, as the Carbon Monoxide NAAQS had not been reviewed since 2011. He stated that the process change of using a pool of consultants instead of a panel was deficient and that valuable input has been lost as a result. He stated that ATS recommends that EPA issue a 2nd Draft ISA, EPA appoint a CASAC Ozone Panel with sufficient expertise, revise the causality determination for all-cause mortality from ozone to likely to be causal, and to revise the causal determination for cardiovascular effects from ozone to likely to be causal.

Jennifer Richmond-Bryant, North Carolina State University, summarized her written comments²⁰ that focused on concerns regarding efforts to curtail the scientific evidence through false narratives about study quality and transparency, concerns about using a narrow interpretation of causality, and addressing points raised by Dr. Cox about the use of exposure surrogates in epidemiology studies in his comments on the Draft PM ISA. Dr. Cox asked her what she meant by his insistence on a narrow test of causation. Dr. Richmond-Bryant indicated that she was referring to the need of epidemiology studies to demonstrate manipulative causality. Dr. Cox indicated that he never stated that epidemiology studies without demonstration of manipulative causality should be thrown out, just that they should not be misinterpreted.

Randy Mandel, Ramboll, presented an oral statement²¹ that focused on deficiencies in Appendix 8 of the Ozone ISA including: oversimplification of summaries of the evidence, technical inaccuracies, failure to substantiate several of its causal effects determinations, and confounding affecting the validity of EPA's conclusions.

Rashid Shaikh, Health Effects Institute (HEI), presented an oral statement²² focused on broadly agreeing with certain key health determinations (evidence for short-term respiratory effects and lack of evidence for cardiovascular effects) summarized in the Ozone ISA and providing information from HEI studies that helped support those conclusions. He indicated that HEI is sponsoring studies looking at effects of low ambient level of ozone, which may shed light on the effects of ozone on all-cause mortality.

John Dale Dunn, Heartland Institute of Chicago, gave an oral statement²³ focused on the ozone science not justifying ozone regulation, the inhalation studies cited by EPA violating basic toxicology scientific rules, there not being any research showing benefits from air quality changes by all the EPA regulations of the past 20 years, CASAC advising EPA 20 years ago that ozone could not be shown to produce adverse health effects at the 0.12 ppm standard at the time, and ozone not being an allergen and not causing asthma.

Stewart Holm, American Forest & Paper Association (AF&PA), presented an oral statement²⁴ focused on the Clean Air Act requirements and AF&PA's comments on several causality determinations in the ISA. He stated that the Clean Air Act does not require the CASAC to approve or reach closure on the ISA and that the Clean Air Act does not require more than one draft of the ISA. He stated that AF&PA supports the use of the new Population Exposure, Comparison, Outcome and Study (or PECOS) approach to identifying and evaluating peer-reviewed publications, and believes that it is an improvement over past ISAs. They agreed with EPA's change in causality determinations that the evidence is only suggestive of a causal relationship for short-term ozone exposure and cardiovascular effects and mortality. They did not agree with EPA's determination that a causal relationship likely exists between short- and long-term ozone exposure and metabolic effects. They urged EPA to reconsider its decision to retain the causal determinations for the relationship between short- and long-term ozone exposure and respiratory effects.

Bob Paine, AECOM, presented an oral statement²⁵ focused on two areas involving background ozone that should be considered for updates in the final ISA. The first area involves stratospheric intrusions and their importance and frequency. He stated that high ozone concentrations at the ground can often be a combination of stratospheric ozone transported from the mid-troposphere and ozone generated from anthropogenic emissions. The other area is the recent trend in ozone concentrations monitored in China. He stated that reduction of particulate emissions in China in recent years has actually led to increases in ozone concentrations in spite of NO_x emission reductions.

EPA Presentation on the Ozone ISA

Dr. John Vandenburg, EPA CPHEA, began EPA's presentation on the Ozone ISA,²⁶ and covered the following slides: EPA Speakers, Outline for Presentation, Introduction and Statutory Requirements, Statutory Requirements: CASAC, Process and Schedule for this Review of the Ozone NAAQS, and Initiation of Expedited Review (May 2018 memo). Dr. Tom Luben, EPA CPHEA, continued the presentation and covered the slides: Overview of the Current Ozone NAAQS, Weight-of-Evidence Approach for Causality Determinations for Health and Welfare Effects, Approach for Evaluation of the Scientific Evidence, Framework for Causality Determinations in the ISA, Purpose and Contents of ISA, Improvements to the Assessment Process for Ozone ISA, Ozone ISA: Overall Observations, Atmospheric Chemistry and Background Ozone, Appendix 1: Atmospheric Chemistry – Overall

Concentrations and Trends, Appendix 1: The Role of Background Ozone, Appendix 2 – Influence of Exposure Error on Epidemiology Study Outcomes, Summary Causality Determinations – Health, Appendix 3: Respiratory Effects and Short-term Ozone Exposure, Appendix 3: Respiratory Effects and Long-term Ozone Exposure, Appendix 5: Metabolic Disease Effects and Short-term Ozone Exposure, Appendix 5: Metabolic Disease Effects and Long-term Ozone Exposure, Appendix 4: Cardiovascular Effects and Short-term Ozone Exposure, Appendix 6: Mortality and Short-term Ozone Exposure, Policy-Relevant Considerations: Health. Dr. Meredith Lassiter continued the presentation and covered the slides: Ecological Effects: Draft Causality Determinations, Ecological Effects, Effects of Tropospheric Ozone on Climate: Draft Causality Determinations, Welfare: Effects on Climate, Summary Causality Determinations – Welfare, Summary – Key Science Points. Dr. John Vandenburg covered the Next Steps for the Ozone ISA, the Ozone Team, and Approach for Evaluation of the Scientific Evidence.

Dr. Lange asked what EPA considered as relevant concentrations for hazard assessment determinations. Dr. Vandenburg stated that for epidemiological studies, they were ambient concentrations, for controlled human exposure studies, they were concentrations around the standard, 60-80 ppm, and for animal toxicological studies, they were higher to gain insights on the mode of action, up to 1-2 orders of magnitude. Dr. Lange asked whether EPA considers dose-dependent transitions in toxicity, that toxicity changes at different doses. Dr. Vandenburg indicated that they represent the data that are available in the studies. Dr. Lange asked how study evaluation integrated into the document itself, into the conclusions that were drawn and how studies were chosen for inclusion in the HAWC database. Dr. Luben indicated that they have always considered study quality when evaluating studies for inclusion in ISAs. All studies included in the ISA are high quality and they have tried to document that more clearly and some examples of that documentation are in the HAWC database. He stated that the narrative approach for study quality evaluation for the health studies were done for those that lead to casual or likely to be causal determinations or whose causal determinations were changed.

Dr. Cox asked whether the ISA reviews all of the studies and key papers that will be used in the PA to quantify risk. Dr. Vandenburg indicated that the ISA is the scientific basis, but that there were additional analyses in the risk and exposure analyses in the PA. Dr. Cox asked if a model were used in the PA to project or calculate risk, whether the strengths and weaknesses and scientific foundation of that model be in the ISA. Dr. Vandenburg stated that the application of the evidence in terms of analyses is provided in the PA. Dr. Cox asked what were the empirically testable implications of determining that a C-R association is causal. Dr. Luben indicated that they were not conducting an experiment or testing a hypothesis in making causal determination, they were using their expert judgment based on the evidence. Dr. Cox asked whether determining a C-R association is causal imply that reducing the concentration would reduce the probability of response. Dr. Vandenburg stated that the expectation is that if you reduce ozone exposure, you would reduce the potential of an adverse health outcome. Dr. Cox asked whether if the concentration were reduced and response did not go down, that would be evidence against the causal determination. Dr. Vandenburg stated that would not necessarily be correct because there are many other factors that may be influencing the population. Dr. Cox asked whether, if all other factors were held constant, would there be an expectation that reducing concentration would reduce response. Dr. Vandenburg stated that there was evidence for that, the controlled human exposure studies. Dr. Cox asked how the causal determinations were validated. Dr. Vandenburg stated that the process included the evaluation by EPA's judgements, input by the CASAC and the public. He indicated that in five years it would be revisited and based on new evidence, the determinations may change. Dr. Cox asked whether the causality determinations were empirically validated. Dr. Vandenburg indicated that there were not performing experiments, but were making judgements based on the scientific evidence. Dr. Vandenburg stated that, as the Administrator pointed out in the Agency's response to the

CASAC PM ISA Report, some of the causality issues brought up by the CASAC are long-term issues and cannot be addressed in the current documents. Regarding the literature review, Dr. Cox asked if they addressed inter-judge reliability in figuring which studies are relevant and how to interpret them. Dr. Luben indicated that exclusion of studies is a team-level decision and that no single scientist can decide to exclude a study. Dr. Cox stated that Pruet et al. (2015) was not included in the ISA and that they applied EPA's same weight-of-evidence approach and did not come to the same conclusions as EPA. Dr. Luben stated that systematic reviews and meta analyses are not considered as primary evidence, but they ensure that every study included in those systematic reviews and meta analyses are evaluated.

Discussion on Responses to the Ozone ISA Charge Questions

Appendix 10 – ISA Development Process

Dr. Cox indicated that Appendix 10 is useful, it lays out principles of the approach that are quite exciting, but did have several comments. He stated that when he did some spot checks, he found that Moore et al. (2008) was included, but that a follow-up paper was not (Moore et al., 2012). He indicated that Moore et al. (2008) found a causal relationship using unverified modeling assumptions but the follow-up Moore et al. (2012) removed the unverified modeling assumptions and did not find a causal relationship. He stated it was not clear why Moore et al. (2012) was not included. Dr. Cox indicated that the non-member consultants did not find the study inclusion/exclusion to be clear or consistently applied. Dr. Cox did find Appendix 10 to be useful and effective in setting aspirational goals, however it was not clear how well the principles were carried out. Dr. Lange indicated that there needed to be more clarity on how study quality was evaluated both at the individual level and how it goes into the document. Dr. Cox stated that they should recommend that EPA consider a color-coded matrix, similar to what Dr. Julie Goodman presented, that would have individual studies on the rows and study quality criteria as columns. There was general consensus among the CASAC members to recommend that the EPA seek further input from the National Academies on the causality framework.

Appendix 1 - Atmospheric Sources and Emissions, Ambient Concentrations of Ozone (including Background Ozone)

Dr. Boylan stated that uncertainties in the emissions inventory should be discussed for each pollutant and source sector. He indicated that there needs to be a discussion of why precursor emissions are important for ozone formation. He stated that there should also be a discussion of how exceptional events are accounted for in health studies and risk analyses. He indicated that there were studies that showed that U.S. background (USB) ozone can be reliably estimated using ambient monitoring data. Dr. Masuca added that discussions of localized, interstate and/or intercity anthropogenic ozone precursors as well as discussions of topographical effects of ozone formation and ozone concentration transport were missing.

Appendix 2 – Exposure to Ozone

Dr. Boylan stated that the discussion on microenvironmental modeling should include additional information on APEX and SHEDS. He indicated that additional discussion should be added for ozone infiltration in vehicles and a detailed discussion of the uncertainties and variability associated with the CHAD, I/O ratios, and P/A ratios should be included. Dr. Lange stated that the ISA should include a more detailed discussion of the impact of exposure measurement error on effects estimates in epidemiology studies.

Appendices 3-7 - Health Effects of Short-term and Long-term Ozone Exposures

Dr. Lange stated that, regarding study quality, it was not clear whether chance, bias, and confounding were explicitly considered in evaluating study results. Regarding accuracy of presentation, she indicated that EPA should provide a balanced summary of the study results for each health endpoint, adequately communicating available positive, negative, and null results. She stated that the EPA should appropriately compare animal to human ozone doses when extrapolating animal exposures to potential human risks, and should present dose information in the biological plausibility discussions. She indicated that the EPA should clearly present study information, results, and discussion in each of the sections, and should provide an accurate and balanced summary of results; and that it is important to include the exposure duration and the exercise level of the participants, particularly for controlled human exposure studies. She stated that the ISA would be strengthened if the EPA discussed the scientific significance of conflicting and/or inconsistent evidence. She indicated that further discussion was needed on dose-responsiveness of effects of ozone exposure in experimental studies and comparability of animal models to human diseases. She indicated that errors and heterogeneity in epidemiology study variables can affect the concentration-response relationship and obscure thresholds and that the EPA should apply methods to address this, including errors-in-variables methods. She stated that the ISA should address the adversity and clinical significance of important health effects and should ensure that all relevant information is included in the study figures and tables. She encouraged the EPA to include both positive and negative studies, as well as information about exposure concentrations, in presenting biologically plausible pathways.

Dr. Lange indicated that, for the causal determinations for both short-term and long-term ozone effects on metabolic endpoints, the evidence does not justify the “likely” determination; and that “suggestive” appears to be a more appropriate designation. She stated that it was not clear why the causal determination for ozone effects on fertility and reproduction was “suggestive” and that it was based on very little data. The other CASAC members agreed.

Dr. Frampton indicated that Figure 3-1 provides an excellent synthesis of known and suspected biological pathways mediating ozone respiratory health effects, but had several suggestions for further refinement. For Appendix 5 on metabolic effects, he concurred with Dr. Lange that the data are not sufficient to support a new causal determination of “likely to be causal.” He stated that a future research need is whether brief stress responses, in the absence of symptoms or other consequences, constituted an adverse health effect. He recommended including additional studies for effects on mortality and cardiovascular effects from short-term ozone exposure. Several members requested that the EPA provide a list of cardiovascular morbidity and mortality studies²⁷ that were excluded from the ISA and then they would identify which additional studies EPA should consider.

Appendices 8-9 – Welfare Effects

Dr. Kendall indicated that the EPA did a really good job evaluating the evidence of ecological effects in Appendix 8. He agreed with the causality determinations of “casual” for visible foliar injury, reduced vegetation growth, reduced plant reproduction, reduced yield and quality of agricultural crops, reduced productivity in terrestrial ecosystems, and alteration of terrestrial community composition. He also agreed with the causal determinations of “likely to be causal” for increased tree mortality, alteration of herbivore growth and reduction, alteration of plant-insect signaling, reduced carbon sequestration in terrestrial ecosystems, and alteration of ecosystem water cycling. He recommended that EPA consider and develop a research plan for a bird model that could be assessed in terms of wildlife toxicology of ozone exposure in warm-blooded vertebrates.

For Appendix 9, Dr. Kendall commended the EPA for continuing to clearly characterize and communicate effects of ozone related to climate change. He agreed with the causal determinations in Appendix 9, but recommended that the EPA consider incorporating further research to better define and quantify the roles of ozone in climate science.

The meeting was recessed at 5:00 pm.

Thursday, December 5, 2019

Discussion on Responses to the Ozone ISA Charge Questions (cont'd.)

Executive Summary, Integrated Synthesis

Dr. Cox indicated that the key information provided in the draft ISA and its Executive Summary is unclear. He stated that concerns about lack of clarity in how key results are derived, expressed, and communicated have been raised in numerous public comments. He indicated that many of the non-CASAC member consultants indicated in their responses to questions that they also did not find the scientific information in the ISA to be clear due to unclear criteria for selecting and weighting studies and how key conclusions are derived from them; unclear description of how, if at all, conclusions would change if consistent criteria were systematically applied; not providing comprehensive quantitative uncertainty and sensitivity analyses; ambiguous, subjective, and sometimes arbitrary causal determination judgements; unclear causal determination meanings and implications for empirical observations; unclear treatment of wildfire contributions to ozone exposure; and unclear discussion of the extent to which ozone-associated physiological effects are transient. He recommended that the Executive Summary include discussion of how public health effects depend on changes in ozone levels; summarized results from a systematic review and critical evaluation and synthesis of relevant studies, including negative ones that have been omitted from the draft ISA; detailed discussion of possible confounding; results of systematic evaluations of study quality using consistently applied criteria; discussion of causal biological mechanisms of inflammation-related health effects; and results of comprehensive, quantitative uncertainty and sensitivity analyses.

Dr. Cox indicated that the Integrated Synthesis has the following limitations: biased selection of studies; literature on nonlinear effects not well covered; summaries of relevant literature are incomplete and of questionable accuracy; policy-relevant science is not addressed; and uncertain relevance of facts addressed.

Mr. Yeow indicated that they were ahead of schedule and that they would proceed with Additional Clarifying Comments on the Ozone ISA, take a break, then have EPA make their presentation on the Ozone PA, keeping public comments on the Ozone PA at the same time, after lunch.

Additional Clarifying Comments on the Ozone ISA

Mr. Yeow indicated that Julie Goodman, Gradient, had initially registered to make a clarifying comment, but could not make it and had submitted written clarifying comments instead,²⁸ which were distributed and posted on the meeting webpage.

Gretchen Goldman, Union of Concerned Scientists, reminded the committee that the framework they were under was the NAAQS regulatory framework and that they were not being asked for academic exercises or to test hypotheses. She stated that the task they were charged with was to look at the strength of the available evidence and that this is what the EPA presented to them. She indicated that if the committee wanted to explore new ways of designing studies and new ways of testing hypotheses, that would be more appropriate for recommendations on future research needs, but was not something that the EPA could address in a synthesis document like the Ozone ISA.

Dr. Cox asked the CASAC members whether they wanted to see another draft of the Ozone ISA. The CASAC members indicated that there was not a need to see another draft of the Ozone ISA.

EPA Presentation on the Ozone PA

Dr. Erika Sasser, EPA OAQPS, began EPA's presentation on the Ozone PA,²⁹ and covered the following slides: Background and Statutory Requirements, Process and Schedule for this Review of the Ozone NAAQS. Dr. Deirdre Murphy, EPA OAQPS, continued the presentation and covered: Purpose of the Policy Assessment, Primary Standard: Overarching Policy-Relevant Question, Primary Standard: Health Effects Evidence, Primary Standard: Overview of Health Effects Evidence. Dr. Stephen Graham, EPA OAQPS, continued the presentation and covered: Primary Standard: Exposure/Risk Information, Primary Standard: Exposure and Risk Analysis - Features of Study Areas, Primary Standard: Exposure and Risk Analysis - Ambient Air Concentrations, Primary Standard: Exposure and Risk Analysis - Estimating Exposure, Primary Standard: Exposure and Risk Analysis - Estimating Risk, Primary Standard: Exposure & Risk Analysis – Risk Estimates, Primary Standard: Exposure and Risk Analysis - Key Uncertainties, Primary Standard: Exposure & Risk Analysis - Main Findings. Dr. Murphy continued the presentation and covered: Primary Standard: Preliminary Conclusions, Secondary Standard: Overarching Policy-Relevant Question, Secondary Standard: Welfare Effects Evidence & Air Quality/Exposure Information, Secondary Standard: Overview of Welfare Effects Evidence, Secondary Standard: Quantitative E-R Relationships with O₃, Secondary Standard: Air Quality/Exposure Information, Secondary Standard: Quantitative E-R Relationships with O₃ (continued), Secondary Standard: Evidence of quantitative relationships (continued), Secondary Standard: Preliminary Conclusions.

Dr. Frampton asked what status the ISA was in during the preparation of the PA. Dr. Murphy indicated that they closely followed and tracked the development of the ISA. Dr. Frampton asked why FEV1 was the sole focus of the risk analysis parameter and airway inflammation seemed to be ignored in the PA. Dr. Murphy indicated that there was not an intention to ignore inflammation and that his comments will help them better and more comprehensively characterize the results. Dr. Frampton indicated that it seemed to him that 70 ppb offered no margin of safety given human clinical studies showing adverse health effects as low as 60 ppb. He asked if EPA could comment further on this. Dr. Murphy stated that it is the Administrator who makes the judgement of adequate margin of safety in judging the adequacy of the standard, whether it needs to be changed or retained. She stated that what they tried to do in the PA was to identify any new information since the last review that may change conclusions from the last review.

Dr. Cox suggested that they break for lunch and continue with questions for EPA after the public comment period.

Public Comments on the Ozone PA

Gretchen Goldman, Union of Concerned Scientists, stated that she had many concerns with the process being followed for the Ozone NAAQS review and questioned whether the expedited review could yield robust science advice to the Administrator. She indicated that previous CASACs recommended a level of 60 – 70 ppb and indicated that 70 ppb may not offer an adequate margin of safety, particularly for sensitive groups such as children and asthmatics.

Julie Goodman, Gradient, was on the phone and presented an oral statement³⁰ that indicated that a review of the evidence and risk-based information indicates that the current standard may be more conservative than necessary to protect public health. She indicated that study quality was not fully or consistently considered in the ISA and that the ISA did not properly consider key limitations in the epidemiology evidence. She recommended an update to the NAAQS systematic review and causal determination framework. She stated that the controlled human exposure studies indicate that there are no statistically significant adverse respiratory effects associated with ozone exposures below 70 ppb, and that effects reported at 60 ppb are not adverse.

Chris Frey, North Carolina State University, presented an oral statement³¹ that indicated that the pool of consultants does not adequately substitute for an Ozone Review Panel, that EPA should appoint an Ozone Review Panel, that reviewing the PA and ISA at the same meeting co-mingles policy considerations before science issues have been resolved, and that CASAC should not ignore sensitive/at-risk subpopulations.

Albert Rizzo, American Lung Association, presented an oral statement³² that indicated that evidence shows harm to sensitive populations at levels well below the current standard of 70 ppb, that children with asthma are worth protecting, that EPA did not evaluate impacts to outdoor workers, and that they recommend a standard no greater than 55 ppb to 60 ppb.

James Enstrom, UCLA (retired) and Scientific Integrity Institute, was not present on the phone and Mr. Yeow indicated they would circle back to him after the rest of the public speakers finished.

Anne Smith, NERA Economic Consulting, was on the phone and presented an oral statement³³ that focused on the Draft PA's estimates of quantitative risks and risk-based considerations. She stated that there are two types of quantitative risks calculated in the Draft PA using the APEX model: exposure risk estimates and lung function risk estimates. She indicated that there were substantial uncertainties around both exposure-response models' estimates, but that it is reasonable to give more weight to lung function risk estimates from the E-R model than the MSS model.

Gary Ewart, American Thoracic Society, was on the phone and raised concerns with the review process, the rushed process, the overlapping documents, and the elimination of panels. He stated that ATS strongly agrees with the ISA's chapter on health effects of ozone exposure to children and that it should weigh heavily in the CASAC's review of the PA, and that the ATS does not believe the current standard to be protective and recommends a standard of 60 ppb.

Chad Whiteman, U.S. Chamber of Commerce, was on the phone and stated that the Chamber was supportive of air quality standards that were necessary to protect public health and public welfare and that their members will take appropriate measures required of them to attain and maintain those standards. He stated that ozone emissions have been reduced by 21% since 1990. He stated that it was important for CASAC to recognize the direct and indirect impacts of a more stringent NAAQS. He

indicated that Section 109d of the Clean Air Act requires the CASAC to advise the Administrator of any adverse public health, welfare, social, economic, or energy effects that may result from attainment or maintenance of such NAAQS. He stated that any revision of the NAAQS should consider the overall impact on economic growth and jobs. He stated that the Chamber recommends that the CASAC encourage the Administrator to retain the current standard.

John Bachmann, presented an oral statement³⁴ that focused on three main points: to thank EPA staff who worked on the Ozone ISA and PA as well as the CASAC members, to recommend future research on trends in alternative averaging times for ozone exposures and potential health effects, and to recommend that CASAC request that EPA conduct the kind of analysis of potential effects of ozone on climate that they requested in their review of the PM secondary standard.

Courtney Taylor, Ramboll, was on the phone and presented an oral statement³⁵ that focused on enhancements to the clarity of the PA. She recommended that EPA emphasize its findings that all monitoring sites with ozone concentrations below the current secondary standard also have a W126 index at or below 17 ppm-hours and that EPA might supplement its analysis by quantifying the probability that a W126 index value exceeding 17 ppm-hr could occur at ambient ozone concentrations below the current level of the secondary NAAQS. She also recommended that EPA include more discussion concerning what is known about the impact of ozone in ambient air on Crassulacean Acid Metabolism (CAM) plants.

John Dale Dunn, Heartland Institute of Chicago, was on the phone and presented his oral statement.³⁶ He stated that the research used by EPA to justify ozone regulations does not meet the basic rules for proof of detrimental health effects.

David Heinold, AECOM, was on the phone and presented his oral statement.³⁷ He stated that he supported EPA's preliminary policy decisions to retain the current primary and secondary NAAQS for ozone. He indicated that the results of EPA's 2019 ozone exposure assessment is consistent with the level of exposure that the U.S Court of Appeals for The District of Columbia Circuit judged to be health protective in its August 2019 decision to retain the 70 ppb primary standard. He stated that analyses presented by EPA indicate that the current secondary standard, which has the same level and form as primary standard, should be retained.

Daren Bakst, The Heritage Foundation, was not present on the phone. Mr. Yeow called on Dr. Enstrom again and he was not present on the phone.

EPA Presentation on the Ozone PA (cont'd.)

Dr. Cox invited EPA back to answer CASAC questions regarding their Presentation on the Ozone PA.

Dr. Boylan asked why CAMx modeling only used 2016 data, whereas APEX modeling used 2015-2017 data. Dr. Graham indicated that the 2016 data from the CAMx models were used to adjust the 2015-2017 ambient concentration data in the APEX model. Dr. Boylan indicated that outdoor workers were not included in the APEX modeling, but were in the 2014 risk assessment, and asked why they were not included. Dr. Graham indicated that they were not included due to limitations on time. Dr. Cox asked whether EPA had any sense of how well the results from MSS modeling compared with results from other health impact function models (such as WHO and other European modeling work). Dr. Graham indicated that they were not that familiar with results from the other models and stated that they relied less heavily on the MSS model results.

Discussion on Responses to the Ozone PA Charge Questions

Chapter 1 – Introduction

Dr. Cox proposed that they use some of the same language from the consensus response to charge question 1 from the CASAC PM PA report. He stated that the final PA should include drawing and preserving key conceptual distinctions between associations and causation; carefully verified evidence and unverified assumptions and models; average and individual exposures; scientific conclusions and expert judgements. He indicated that the PA should also include emphasis on more effective integration of information from animal toxicology and controlled human exposure studies to better characterize causal biological C-R functions for pulmonary inflammation and other physiological responses. Dr. Frampton took issue with the recommendation that the PA needed to include distinguishing between scientific conclusions and expert judgements since that was more for the ISA. Dr. Cox agreed and stated that they will use the same language as agreed to for the consensus response to charge question 1 from the CASAC PM PA Report.

Dr. Cox stated that the PA can more fully realize their stated intentions by summarizing available empirical evidence on how changes in public health effects depend on changes in ozone levels; accurately summarizing results from a systematic review and critical evaluation and synthesis of relevant studies relied on to reach conclusions; clearly distinguishing between causal C-R functions and regression C-R functions; discussing in more detail the health and policy implications of causal biological mechanisms of inflammation-related health effects in general and sensitive populations; quantifying uncertainty and variability in risk predications; and more thoroughly addressing effects of ozone on climate change.

Chapter 2 – Air Quality

Dr. Boylan recommended adding discussions of precursor emissions and their relative importance to ozone formation, uncertainties associated with precursor emission pollutants and sources, precursor trends, differences in seasonality and trends within and between different regions of the United States. He indicated that the treatment of ozone exposures related to wildfires and exceptional events should be expanded and clarified.

Chapter 3 – Review of the Primary Standard

Dr. Lange stated that the PA should provide a more balanced reporting of data and analyses, should more fully support the conclusions being drawn, including providing additional policy-relevant information and caveats about study limitations to air pollution epidemiology studies, ensuring data and analyses are clearly reported, and adding a quantitative uncertainty and variability analysis.

Dr. Frampton expressed concern with reviewing the ISA and PA simultaneously when the PA is supposed to depend on findings from the ISA. He stated that CASAC should be provided with the opportunity to review, comment on, and receive responses from EPA on the ISA, before any consideration of the PA. He also stated his concern about the lack of epidemiologists and lack of expertise to conduct these reviews. He indicated that not having a panel of experts at the table with the CASAC to deliberate with them limited the quality of advice that CASAC could provide. The CASAC agreed to include a recommendation that it see a second Draft PA that is prepared after the ISA is completed. Dr. Cox asked if CASAC wanted to soften that recommendation to see a Second Draft PA, if possible, for both the ozone PA and PM PA. The CASAC did not want to soften that recommendation.

The meeting was recessed at 5:00 pm.

Friday, December 6, 2019

Discussion on Responses to the Ozone PA Charge Questions (cont'd.)

Chapter 3 – Review of the Primary Standard (cont'd.)

Dr. Frampton was concerned with the precedent being set in the CASAC NAAQS reviews of reducing the expertise available in the reviews by not having panels/experts they could deliberate with. He suggested that the CASAC make the recommendation that for future reviews, the process should return to the previous practice of having a broad expert panel that does not just answer written questions, but can participate in public meetings and deliberate with the CASAC. The other CASAC members agreed and were supportive of including that recommendation.

Dr. Frampton indicated that he was concerned about the essentially exclusive use of lung function decrements in assessing ozone risk. He stated that this does not adequately consider other respiratory effects that are likely to be important in people with respiratory diseases such as asthma. He indicated that the analyses do not adequately consider the risks for people with asthma and questions whether 70 ppb is adequate to protect public health with an adequate margin of safety. The other CASAC members agreed regarding the limitations of looking at just FEV1 and that it was an important research need but did not find compelling evidence that 70 ppb was not protective of public health with an adequate margin of safety.

Dr. Cox indicated that the PA omitted important caveats about using the MSS model, similar to what the EPA had provided in EPA's 2014 Ozone HREA. He stated that the final PA should discuss the internal and external validity of the risk models and their predictions and should present the results of empirical validation tests for the risk models and predictions. Dr. Boylan had comments on the selection of study areas, CAMx model use, and ozone model performance evaluation.

Dr. Cox asked (by show of hands) how many of the CASAC members thought that there was sufficient new evidence to justify changing the previous NAAQS decision (holding aside whether the previous NAAQS decision was justified). None of the CASAC raised their hands. Dr. Cox asked (by show of hands) how many of the CASAC members disagreed with EPA's conclusion that consideration should be given to retaining the current primary standard of 70 ppb and that it is appropriate to consider the 70 ppb to be adequate. Dr. Frampton raised his hand to indicate that he disagreed with EPA's conclusion and the other CASAC members agreed with EPA's conclusion. Therefore the CASAC did not come to consensus and both viewpoints will be represented in the report.

Chapter 4 – Review of the Secondary Standard

Dr. Kendall indicated that the approach he took was to evaluate whether the science supports the conclusions made in the PA. He provided background on the current secondary standard and considerations regarding the adequacy of the prior standard. He stated that the newly available evidence in the current review supports, sharpens, and expands upon the conclusions reached in the previous Ozone NAAQS review. He indicated that the preliminary conclusion by the U.S. EPA that the 2015 decision to revise the level of the Secondary Standard for ozone to 70 ppb, in conjunction with retaining the indicator, averaging time, and form, appears to be working in maintaining ambient air concentrations

of ozone across the United States at levels that are protective for the public welfare, particularly as related to vegetation. He agreed with the EPA that Relative Biomass Loss (RBL), is a scientifically sound surrogate of a variety of adverse effects that could be exerted to public welfare. He also agreed with the EPA that information available in the present review does not call in to question this RBL approach, indicating that there continues to be support for the use of tree seedling RBL as a proxy for the broader array of vegetation related effects, most particularly those related to growth that could be impacted by ozone. He also indicated that a future research need was to enhance the research on the role of ozone on climate science. Dr. Boylan stated that it was not clear whether the recent remand of the secondary standard due to the EPA not providing sufficient justification was adequately addressed in the PA. The CASAC members were unanimous in finding that the available evidence does not reasonably call into question the adequacy of the current secondary ozone standards and concurs with the EPA that they should be retained.

Future Research

Dr. Cox indicated that the chapter leads will summarize the research needs that were discussed during the deliberations and asked whether there were any other research needs that had not yet been discussed. Dr. Boylan indicated that there should be an expansion of the PAMS monitoring from three months to six months (April through October), since peak ozone concentrations have been shifting from summer to late spring and early fall. Dr. Frampton stated that there should be further research into the metabolic effects of ozone.

Additional Clarifying Comments on the Ozone PA

James Enstrom, UCLA (retired) and Scientific Integrity Institute, was not present on the phone and Mr. Yeow indicated they would circle back to him after the rest of the public speakers finished.

Gretchen Goldman, Union of Concerned Scientists, stated that CASAC's review has nothing to do with decisions that the previous Administration had made, but had everything to do with what the scientific evidence supports, and to consider what previous science advice was. During the previous review, that advice came from a former CASAC that was augmented by nearly 20 experts that had the breadth, depth, and diversity of expertise that was needed to assess the ozone standards. She stated that it was CASAC's responsibility to comment on the degree to which the standards protect public health with an adequate margin of safety, especially for sensitive subpopulations.

John Bachmann, wanted to clarify that his research recommendations were on: 1) doing more work on trends in alternative averaging times for ozone exposure and potential health effects; and 2) to recommend that CASAC request that EPA conduct the kind of analysis of potential effects of ozone on climate that they requested in their review of the PM secondary standard.

Mr. Yeow called on Dr. Enstrom again, who was not present on the phone.

The meeting was adjourned by Mr. Yeow at 12:00pm.

Respectfully Submitted:

Certified as Accurate:

/s/

/s/

February 27, 2020

Mr. Aaron Yeow
Designated Federal Officer
EPA SAB Staff Office

Dr. Louis Anthony Cox, Jr.
Chair
CASAC

Date

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Committee members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Committee members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings.

Materials Cited

The following meeting materials are available on the CASAC December 3-6, 2019, meeting webpage: <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/A0D0F9D4C6BC36D88525848C00467771?OpenDocument>

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- ¹ 11-13-19 Draft CASAC Review of the EPA's Policy Assessment for the Review of the NAAQS for PM (External Review Draft – September 2019)
 - ² Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019)
 - ³ Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019)
 - ⁴ Chartered CASAC Roster
 - ⁵ Federal Register Notice Announcing the Meeting
 - ⁶ Agenda
 - ⁷ List of Registered Public Speakers
 - ⁸ PM PA Comments from Lianne Sheppard, University of Washington
 - ⁹ PM PA Comments from Lianne Sheppard, University of Washington
 - ¹⁰ PM PA Oral Statement from Sumita Khatri, American Lung Association
 - ¹¹ PM PA Oral Statement from Thomas Golab, American Council on Science and Health
 - ¹² PM PA Oral Statement from Dan Greenbaum, Health Effects Institute
 - ¹³ PM PA Oral Statement from John Dale Dunn, Heartland Institute, Chicago
 - ¹⁴ PM PA Oral Statement from Daren Bakst, The Heritage Foundation
 - ¹⁵ PM PA Oral Statement from Rob McConnell, University of Southern California
 - ¹⁶ Ozone ISA Oral Statement from Peter Valberg and Julie Goodman, Gradient
 - ¹⁷ Ozone ISA Oral Statement from H. Christopher Frey, North Carolina State University
 - ¹⁸ Ozone ISA and Ozone PA Comments from the Former CASAC Ozone Panel
 - ¹⁹ Ozone ISA Oral Statement from David Hill, American Lung Association
 - ²⁰ Ozone ISA Comments from Jennifer Richmond-Bryant, North Carolina State University
 - ²¹ Ozone ISA Oral Statement from Randy Mandel, Ramboll
 - ²² Ozone ISA Oral Statement from Rashid Shaikh, Health Effects Institute
 - ²³ Ozone ISA and Ozone PA Oral Statement from John Dale Dunn, Heartland Institute, Chicago
 - ²⁴ Ozone ISA Oral Statement from Stewart Holm, American Forest & Paper Association and American Wood Council
 - ²⁵ Ozone ISA Oral Statement from Robert Paine, AECOM
 - ²⁶ EPA Presentation - Review of the Integrated Science Assessment for Ozone
 - ²⁷ Short-Term Cardiovascular Morbidity and Mortality Studies Excluded from the Draft Ozone ISA Based on Location
 - ²⁸ 12-4-19 Ozone ISA Clarifying Comment from Julie Goodman, Gradient
 - ²⁹ EPA Presentation - Policy Assessment for the Review of the Ozone National Ambient Air Quality Standard
 - ³⁰ Ozone PA Oral Statement from Peter Valberg and Julie Goodman, Gradient
 - ³¹ Ozone PA Oral Statement from H. Christopher Frey, North Carolina State University
 - ³² Ozone PA Oral Statement from Albert Rizzo, American Lung Association
 - ³³ Ozone PA Oral Statement from Anne Smith, NERA Economic Consulting
 - ³⁴ Ozone PA Oral Statement from John Bachmann
 - ³⁵ Ozone PA Oral Statement from Courtney Taylor, Ramboll
 - ³⁶ Ozone PA Oral Statement from John Dale Dunn, Heartland Institute of Chicago
 - ³⁷ Ozone PA Oral Statement from David Heinold, AECOM

ATTACHMENT A – Other Attendees

Members of the Public who Attended All or Part of the Meeting

Name	Affiliation
Allen, George*	
Ambrozaitis, Giedrius*	Alliance of Automobile Manufacturers
Aung, Hnin Hnin*	
Avey, Lance*	EPA
Bachmann, John	Environmental Protection Network
Bacon, Taylor*	
Bahadori, Tina*	EPA
Bakst, Daren*	The Heritage Foundation
Baxter, Lisa	EPA
Becker, Michelle	EPA
Benromdhane, Souad*	EPA
Bhetraratana, May*	California Air Resources Board
Blase, Kurt*	
Brimmer, Amanda*	Denver Regional Air Quality Council
Buckley, Barbara	EPA
Byrley, Peter	EPA
Chan, Elizabeth	EPA
Coffman, Evan*	
Copley, Bruce	ExxonMobil Biomedical Sciences, Inc.
Cory-Slechta, Deborah*	
Coughlin, Justin*	EPA
Dahmen, Gregg*	Oregon DEQ
Daniels, Rebecca	EPA
Dolwick, Pat*	EPA
Dunn, John Dale*	Heartland Institute of Chicago
Dutton, Steven	EPA
Edwards, Lariah*	Gradient
Enstrom, James*	UCLA (retired) and Scientific Integrity Institute
Ewart, Gary*	American Thoracic Society
Fann, Neal	EPA
Ferko, Jessica*	
French, Tim*	Truck and Engine Manufacturers Association
Frey, Chris	North Carolina State University
Golab, Thom*	American Council on Science and Health
Goldman, Gretchen	Union of Concerned Scientists
Goodman, Julie	Gradient
Gorman, Teresa*	

Name	Affiliation
Graham, John*	Clean Air Task Force
Greenbaum, Dan*	Health Effects Institute
Guillen, Alex*	
Hagan, Nicole	EPA
Hashimoto, Hayden*	Clean Air Task Force
Hassan, Iman	EPA
Heinold, David*	AECOM
Hemming, Brooke	EPA
Henderson, Barron	EPA
Herrick, Jeff	EPA
Hill, David G.*	American Lung Association
Hines, Erin*	EPA
Hogue, Cheryl*	Chemical & Engineering News
Holm, Stewart*	American Forest & Paper Association
Hutson, Mary	EPA
Igoe, Sheila*	EPA
Isied, Maggie*	
Itkin, Cheryl*	EPA
Jansen, John*	None
Jarabek, Ann*	EPA
Jenkins, Scott	EPA
Jerry, Roger*	South Carolina Department of Health and Environmental Control
Jones, Rhea	EPA
Kalisz, Cathe*	
Katz, Stacey*	EPA
Kaylor, Doug	EPA
Kelly, Jim	EPA
Khatri, Sumita*	American Lung Association
Kilby, Nick*	
Kopits, Elizabeth*	EPA
Lamichhane, Archana	EPA
Lamson, Amy*	EPA
Langstaff, John	EPA
Langworthy, Cindy	Hunton
Lavelle, Marianne*	
Lavoie, Emma	EPA
Lefohn, Allen S.*	A.S.L. & Associates
Liljegren, Jenny	EPA
Liu, Alisa*	EPA
Lloyd, Christine*	EPA
Luben, Tom	EPA

Name	Affiliation
Madden, Glenda*	
Madden, Renee*	
Mandel, Randy*	Ramboll
Marshall, Kristin*	Boeing
Masinter, Alan*	
McConnell, Rob*	University of Southern California
McDow, Steve	EPA
Meyer, Leigh*	EPA
Miles, Kenyatta*	
Miller, Paul*	Baton Rouge Clean Air Coalition
Milloy, Steve*	junkscience.com
Miyasato, Lori*	California Air Resources Board
Mudasiru, Omdbola	American Petroleum Institute
Nichols, Jennifer	EPA
O'Keefe, Robert*	Health Effects Institute
Orlin, David*	EPA
Owen, Russell*	EPA
Paine, Bob*	AECOM
Parker, Stuart*	IWP News
Peppers, Mel*	EPA
Pekar, Zach	EPA
Perlmutter, Lars	EPA
Plautz, Jason*	Media
Popovech, Marusia*	ExxonMobil Biomedical Sciences, Inc.
Rauch, Molly*	
Reilly, Sean	E&E News
Reyes, Jeanette	EPA
Rice, Byron	EPA
Richmond, Harvey	
Richmond-Bryant, Jen	North Carolina State University
Ridley, Caroline	EPA
Rives, Karin*	
Rizzo, Albert*	American Lung Association
Robarge, Gail M.*	EPA
Sacks, Jason	EPA
Saiyid, Amena	Bloomberg Environment
Sax, Sonja*	Ramboll
Shaikh, Rashid*	Health Effects Institute
Sheppard, Lianne	University of Washington
Shrestha, Lalita*	
Silverman, Steven*	Environmental Defense Fund

Name	Affiliation
Simmons, Jane Ellen	EPA
Simon, Heather	EPA
Sloan, J.*	
Smith, Anne*	NERA Economic Consulting
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