

**Summary Minutes of the  
U.S. Environmental Protection Agency (EPA)  
Chartered Clean Air Scientific Advisory Committee (CASAC)  
Public Teleconference on Ozone  
November 29, 2018**

Date and Time: Wednesday, November 29, 2018 10:00 AM – 2:00 PM ET

Location: Telephone and audio webcast.

Purpose: To provide advice on the EPA's *Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)*.

Participants: Chartered CASAC Members (also see roster<sup>1</sup>)

Dr. Tony Cox, Chair

Dr. James Boylan

Dr. Mark Frampton

Dr. Sabine Lange

Dr. Timothy Lewis

Dr. Corey Masuca

Dr. Steven Packham

Mr. Aaron Yeow, Designated Federal Office (DFO)

Dr. Erika Sasser, EPA Office of Air Quality and Planning Standards (OAQPS)

Dr. Deirdre Murphy, EPA OAQPS

Dr. John Vandenberg, EPA National Center for Environmental Assessment (NCEA)

Dr. Tom Luben, EPA NCEA

Other Attendees (See Attachment A)

### **Introductory Remarks, Panel Introductions, and Review of Agenda**

Mr. Aaron Yeow, DFO, opened the meeting. He noted that, as required under the Federal Advisory Committee Act (FACA), the Panel's deliberations are held in public, with advanced notice given in the Federal Register,<sup>2</sup> and that the meeting minutes will be made publicly available after the meeting. He noted that there was a public comment period noted on the agenda for members of the public who registered in advance with the SAB Staff Office to make oral comments. He noted that the CASAC did receive written public comments, which were posted on the meeting webpage. He stated that the SAB Staff Office determined that there were no issues with conflict-of-interest nor any issues with an appearance of a lack of impartiality for any of the CASAC members. He then turned the meeting over to Dr. Tony Cox, Chair of the CASAC.

Dr. Tony Cox welcomed everyone and had the CASAC members introduce themselves. He then provided an overview of the Agenda<sup>3</sup> and asked the EPA to begin their presentation.

## **EPA Presentation on the Draft Ozone IRP**

Dr. Erika Sasser, EPA OAQPS, introduced the EPA presentation,<sup>4</sup> and focused on EPA Speakers, Outline for Presentation, Statutory Requirements for the NAAQS, Initiation of Expedited Review (May 2018 Memo), and Timeline and CASAC Role. Dr. Deirdre Murphy, EPA OAQPS, continued the presentation, focusing on Planning for this Review: Current Ozone National Ambient Air Quality Standards (NAAQS), Current Air Quality, and Role of the Integrated Review Plan (IRP). Dr. John Vandenberg, EPA NCEA, continued the presentation and focused on the Planning for this Review: Integrated Science Assessment, Developing the Integrated Science Assessment (ISA): Example for Health Criteria, and Framework of Causality Determinations in ISA. Dr. Deirdre Murphy, EPA OAQPS concluded the presentation, focusing on Planning for this Review: Risk and Exposure Assessment, Policy Assessment, and Organization of Integrated Review Plan.

## **Public Comments**

Dr. H. Christopher Frey, North Carolina State University, gave an oral statement focused on changes to CASAC and the NAAQS process since October 2017 without input from CASAC and the public. He stated that these changes harm the quality, credibility, and integrity of the NAAQS review process. He referred to written comments from former members of 2009-2014 CASAC Ozone Review Panel,<sup>5</sup> which contains 7 major findings and 30 recommendations for CASAC. He stated that the Chartered CASAC does not have the breadth and depth of expertise needed to conduct the Ozone NAAQS review.

Dr. Julie Goodman, Gradient, gave an oral statement<sup>6</sup> on behalf of Gradient, but noted that her time spent preparing the comments and calling into the teleconference was funded by the American Petroleum Institute. Her comments focused on the lack of specific instructions for a thorough, systematic, and reproducible analysis; the need for improved detailed individual study quality criteria; and the causal framework being biased towards causal conclusions.

Dr. Gretchen Goldman, Union of Concerned Scientists, gave an oral statement<sup>7</sup> focused on concerns about the process of the Ozone NAAQS review. She stated that the expedited schedule and document merging, combined with gaps in expertise on CASAC and the lack of review panel and public input opportunities are likely to undermine the ability of the EPA to set a science-based standard for ozone.

Dr. Albert Rizzo, American Lung Association, provided comments<sup>8</sup> focused on concerns about changes in the Ozone NAAQS review process and by the curtailed review proposed in the IRP. He urged EPA to restore the CASAC Ozone Review Panel, to not merge review documents, and opposes the last two standardized charge questions on background and adverse economic effects of the NAAQS.

## **Discussion of the IRP Discussion Areas and IRP**

### *Chapters 1 (Introduction) and 2 (Background)*

Dr. Masuca found that Chapter 1 does a good job of describing the legislative history and is a good introductory chapter. He noted that Chapter 2 adequately captures the reductions in ozone concentrations over time due to reductions in precursor emissions. He also pointed to new datasets from NCORE monitoring sites, Photochemical Assessment Monitoring System (PAMS), and near-road monitoring systems. He also indicated that a discussion of transport issues needed to be added.

Dr. Boylan agreed with many of the public comments and was concerned with the aggressive schedule described in Chapter 1, with EPA's plan for just one draft of the documents, and with the proposed merging of the Risk and Exposure Assessment (REA) and Policy Assessment (PA) documents. He stated that the REA should be a standalone document, reviewed by the CASAC and public, prior to the release of the PA. He stated that getting high-quality documents was much more important than meeting the October 2020 deadline. Dr. Cox agreed that the CASAC's most important consideration is to get high-quality documents but was also hopeful that this could be done while still meeting the aggressive schedule. If it turns out not to be possible, he supported requesting whatever changes or help might be necessary to guarantee ending up with a quality product. Dr. Frampton agreed that the quality of the documents is the primary concern but that if they feel the need to review a second draft of a particular document, that they should do so. Dr. Lange stated that it was important to have enough space between documents that comments on one could adequately inform the next one. Dr. Lewis agreed with some of the public commenters that an ozone panel should be formed. Dr. Frampton agreed that panels provide valuable expertise and different perspectives that really strengthen the process and the resulting documents. He added that EPA should form an ozone review panel in time for the review of the ISA. Dr. Boylan expressed his support for creating an ozone panel as well.

### *Chapter 3 (Approach for Review of the Primary and Secondary Standards)*

Dr. Packham stated that his role was to represent the science of toxicology. He stated that the scientific issues in Chapter 3 of the IRP came back to the issues of causation, which is going to be a function of what the mechanism of action is of ozone on biological systems, particularly the lining of the lung. He indicated that there needs to be input/discussion of adverse health effects, defining them or distinguishing them from other kinds of biological effects or response. He stated that the issue of margin of safety was related to the issue of threshold. Dr. Lewis mentioned that asthma seemed to be a major factor that characterizes one of the sensitive populations and was not sure of the cause of asthma, whether it is idiopathic, related to allergen exposure, or other air pollutants. Regarding the secondary standard, he was glad the agency will be considering other photochemical oxidants besides ozone. Dr. Boylan encouraged the agency to consider race and obesity as possible additional factors in defining at-risk populations and pointed to CASAC comments on the primary SO<sub>2</sub> standard. Regarding the current form, he suggested the agency evaluate an integrated form, which should provide a better representation of the continuum of health effects associated with increasing ozone concentrations. Dr. Lange indicated that it is important to integrate toxicology with population studies and that looking at dosimetry in that evaluation is very important.

### *Chapter 4 (Science Assessment)*

Dr. Frampton indicated that the proposed organization of the ISA represents a major change from previous ISAs, where the main body of the ISA will be an integrated synthesis and the reviews of the scientific studies that form the basis for the causality and risk assessments will be relegated to appendices. He stated that the scientific data that form the basis for the NAAQS should remain front and center in the main body of the document. The IRP provides a good description of methods to be used for assessing study quality but is missing a discussion of how this will be used in the review process and standard setting. One issue that should be introduced in the draft IRP is the divergence between epidemiology and clinical studies in the ozone concentration at which health effects are observed and the possible reasons for the divergence, such as the possibility that ambient ozone is a surrogate for other ambient oxidant pollutants that cannot be adjusted for in multipollutant models. Dr. Frampton stated that he was confused by Dr. Cox's use of different terminology for different kinds of causality. He stated that determining causality come from a variety of levels of evidence and trying to divide the idea of causality

into various degrees based on the support of evidence muddies the water. Dr. Cox indicated that there are different distinct concepts of causality, each of which has well-developed literature, definitions, and criteria, which are different than the IARC/Hill criteria, which involves more general reasoning with qualitative considerations. He stated that to support good policymaking, the kind of causation that is most important is manipulative causation. If exposure is changed, how will that change the effect? Sound scientific information that will be useful to policymakers should address manipulative causation and not stop short with only associational causation. Dr. Lange stated that she would like to see a clearer, more objective specification of how the evidence will be weighed and integrated in causality determinations. Dr. Cox appealed to EPA to address a few things with greater clarity. When a determination of causality is made: 1) what kind of causality is it being made for? 2) what kind of effect is it being made for (controlled direct effects, natural direct effects, total effect, indirect effects, mediated effects, etc.)? and 3) what fraction of an association is causal? He also appealed to EPA to be meticulous in distinguishing between causation and association. Also, whenever the word “relationship” were used, EPA should be very clear to specify which type of relationship was being referred to (association, manipulative causation, predictive causation, associational causation, etc.).

#### *Chapter 5 (Quantitative Risk and Exposure Assessment)*

Dr. Boylan found that Chapter 5 adequately describes the planned REA analyses. He noted that the proposed models were appropriate. However, he was concerned about the potential reduction in the number of study areas and scenarios given that significant changes have occurred in ambient ozone concentrations and spatial patterns of high ozone concentrations since the previous review. He also believed that the EPA should include the epidemiological-based risk approach in the current review and details of the REA analyses (how model performance analyses will be performed, how biases in models will be accounted for, etc.) should be included in a REA Planning Document. Dr. Cox reiterated the importance of looking at how changes in exposure will change risks in populations and using that language of manipulative causation throughout the document. He noted that this is especially important in Chapter 5’s discussion of concentration-response relationships. The use of BENMAP for risk assessment may not be conceptually sound because the concentration-response information in BENMAP is explicitly associational, not manipulative.

#### *Chapters 6 (Policy Assessment) and 7 (Proposed and Final Decisions)*

Dr. Lange noted that EPA’s plan for merging REA information into the PA is not described in Chapter 6 of the IRP and should be added. She also recommended that EPA describe how changes in the REA information would be addressed in the PA. A definition or discussion of “unacceptable risks to public health” should be included in the document. There should be more information provided about what will be included in the public docket of the proposed rule in terms of the evidence base.

#### **Public Clarifying Comments**

Dr. H. Christopher Frey, North Carolina State University, made a clarifying statement. He was concerned that the discussion of different types of causality was setting too high an expectation for what could be achievable in this review, that there needed to be a balance between the latest cutting-edge methodology versus what was well-established in the air pollution literature. He also stated that the statutory mandate of the NAAQS states that the standard must be requisite to public health with an adequate margin of safety, not that mechanistic causality must be demonstrated.

Dr. Cox stated that there is substantive literature in air pollution epidemiology that does draw these distinctions in causality, particularly Health Effect Institute (HEI) accountability studies. He stated that although the statutory mandate of the NAAQS does not state that mechanistic causality must be demonstrated, protection of public health itself is a causal concept. Protection has to do with reducing risk, trying to discover how to cause the desired reduction in risk.

Dr. Frampton stated that trying to restructure the casual framework that the EPA has been using for decades for multiple pollutants would generate a lot of controversy, a lot of discussion, and revisiting consensus that had already been arrived at. He liked the idea of exploring new literature on manipulative causality and that the different causality terminology should be added as an acknowledgement of the literature in this area. However, he did not agree with insisting that the current casual framework be changed. The existing causal framework is based on the Hill criteria and has stood the test of time and multiple CASAC reviews.

Dr. Cox clarified that he was not insisting on the causality framework being changed, but that an important limitation of the causality framework is that it is unclear what it really means when something is determined to be causal. He agreed that it would be a mess to try to replace the current framework that is central to the structure and organization of the review. But at the same time, the bar needs to be raised by adding quantitative information and clarity about what is being asserted in the causality determinations.

### **Summary and Next Steps**

Dr. Tony Cox discussed action items.

The meeting was adjourned by Mr. Yeow at 2:00 pm.

Respectfully Submitted:

Certified as Accurate:

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/s/

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Mr. Aaron Yeow  
Designated Federal Officer  
EPA SAB Staff Office

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Dr. Louis Anthony Cox, Jr.  
Chair  
CASAC

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Panel members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Panel 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 website:

<https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/DD656BF1C5C46B5D85258328005AB362?OpenDocument>

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<sup>1</sup> Chartered CASAC Roster

<sup>2</sup> Federal Register Notice Announcing the Meeting

<sup>3</sup> Agenda

<sup>4</sup> EPA Presentation - Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards

<sup>5</sup> Written Comments from Former Members of 2009-2014 CASAC Ozone Review Panel

<sup>6</sup> Oral Statement from Julie Goodman, Gradient

<sup>7</sup> Written Comments from Gretchen Goldman, Union of Concerned Scientists

<sup>8</sup> Oral Statement from Albert Rizzo, American Lung Association

**ATTACHMENT A – Other Attendees  
CASAC November 29, 2018 Public Teleconference**

<b>Name</b>	<b>Affiliation</b>
Allen, George	
Aniagu, Stanley	Texas Commission on Environmental Quality
Bachman, Ammie	ExxonMobil Biomedical Sciences Inc.
Bachmann, John	Environmental Protection Network
Bahadori, Tina	USEPA
Balcanoff, Haley	
Berkey-Ames, Laura	National Association of Manufacturers
Billings, Paul	American Lung Association
Blase, Kurt	Blase Law Group
Brennan, Tom	USEPA
Brown, James	USEPA
Bryant, Christopher	Bergeson & Campbell PC
Carpenter, Tom	USEPA
Copley, Bruce	ExxonMobil Biomedical Sciences Inc.
Downs, Tom	Maine Department of Environmental Protection
DuBois, Sue	
Escoriza, Miguel	Scenic America
Ewart, Gary	American Thoracic Society
Fann, Neal	
French, Timothy	Truck and Engine Manufacturers Association
Frey, Chris	North Carolina State University
Glenn, Barbara	
Goldman, Gretchen	Union of Concerned Scientists
Goodman, Julie	Gradient
Graham, Nancy	INCOG
Greenbaum, Dan	Health Effects Institute
Guillen, Alex	
Hines, Erin	
Hodson, Elke	Office of Information and Regulatory Affairs
Hogue, Cheryl	
Hooghan, Priyanka	
Hossain, Natalie	
Irby, Sebastian	
Jarabek, Annie	USEPA
Jenkins, Scott	USEPA
Jones, Samantha	USEPA
Kalisz, Cathe	American Petroleum Institute

Knickmeyer, Ellen	Associated Press
Lamson, Amy	USEPA
Langworthy, Cindy	Hunton Andrews Kurth LLP
Lefohn, Allen	A.S.L. & Associates
Liu, Coco	Electric Power Research Institute
Malashock, Daniel	USEPA
McDow, Stephen	
Medeiros, Kevin	
Miles, Kenyatta	
Moutinho, Jennifer	ExxonMobil
Narvaez, Jenny	NCTCOG
Nashashibi, Omar	The Franklin Partnership
Nolen, Janice	American Lung Association
Ollison, Will	American Petroleum Institute
Paciga, A.	
Palasits, Sara	House Science Committee
Parker, Stuart	IWP News
Parkhurst, Daniel	
Peppers, Mel	USEPA
Phalen, Robert F.	University of California, Irvine
Rappazzo, Kristen	
Reilly, Sean	E&E News
Reyes, Jeanette	
Rice, Byron	USEPA
Richmond, Harvey	harvey4climateaction
Richmond-Bryant, Jennifer	USEPA
Rizzo, Albert	American Lung Association
Rohr, Annette	EPRI
Ross, Mary	USEPA
Rowland, Kerri	Lower Colorado River Authority
Sacks, Jason	USEPA
Saiyid, Amena H.	Bloomberg Environment
Sandiford, Vicki	USEPA
Sauerhage, Maggie	USEPA
Shallal, Sue	USEPA
Sloan, J.	
Stallworth, Holly	USEPA
Steichen, Ted	American Petroleum Institute
Wayland, Robert	USEPA
Weaver, Chris	
Webster, Martha	
Wulf, Brian	Exxon Mobil Corporation