

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Chartered Clean Air Scientific Advisory Committee (CASAC)
Public Meeting on Ozone
February 11-12, 2020**

Date and Time: Tuesday, February 11, 2020 - Wednesday, February 12, 2020

Location: Telephone and live audio webcast.

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

Participants: Chartered CASAC Members (also see roster³)

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)

Other Attendees (See Attachment A)

Tuesday, February 11, 2020

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 advanced notice given in the Federal Register.⁴ He stated that FACA required that public meetings allow for public comment and that there was a public comment period noted on the agenda⁵ where members of the public, who have registered in advance, could make public comments. He indicated that written public comments have been received and were distributed to the CASAC and posted on the CASAC meeting webpage. 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 an appearance of a loss of impartiality for any of the CASAC members. He turned the meeting over to Dr. Tony Cox, CASAC Chair.

Dr. Cox welcomed everyone and stated that the goal for the day was to work through the Draft CASAC Ozone ISA Report. He reminded CASAC members to keep separate science considerations for the ISA and policy considerations for the PA.

Public Comments on Draft CASAC Ozone ISA Report and Draft CASAC Ozone PA Report

Mr. Yeow indicated that they would proceed in the order presented in the List of Registered Public Speakers.⁶ 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.

Chris Frey, North Carolina State University, stated that he was a past chair of the CASAC and past chair of the CASAC Ozone Review Panel from 2012-2014. He indicated that he had three main points: 1) that CASAC lacks the breadth, depth, and diversity of expertise, experience, and perspectives needed for the NAAQS review; 2) CASAC is imposing a normative risk-seeking decision context for this review; 3) CASAC is not adequately taking into account at-risk populations.

Gretchen Goldman, Union of Concerned Scientists, stated that CASAC should consider and heed the input of relevant experts on ozone pollution and health and welfare effects, particularly the 18 members of the previous CASAC Ozone Review panel from 2009-2015. She indicated that the previous CASAC Ozone Review Panel informed the CASAC in 2014 that although 70 ppb was included in the recommended range of the standard, that it may not provide an adequate margin of safety.

Julie Goodman, Gradient, presented an oral statement⁷ that indicated that the individual CASAC member comments on both the Ozone ISA and PA were extensive, with considerable depth and detail, and had a solid scientific basis. She stated that, as indicated in the CASAC letter, the ISA does not conduct a comprehensive systematic review of the health effects evidence, and study quality and biological plausibility pathways are not always fully or consistently considered. She agreed with the CASAC report on the Ozone PA that stated the PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current ozone annual standard.

David Hill, American Lung Association, presented an oral statement⁸ that focused on the changes to the NAAQS review process, including not forming an ozone review panel, and stated that they disagreed with many of CASAC's comments in the Draft CASAC Ozone ISA and PA reports. He stated that the American Lung Association does not agree that the current ozone standard protects public health with an adequate margin of safety and recommends a standard no greater than 55 – 60 ppb to protect public health. Regarding Dr. Hill's comment that the causal determinations in the ISA and ISA Preface were not ambiguous, Dr. Cox asked Dr. Hill whether the ISA Preface clearly defines whether a designation of causal means necessary causation, sufficient causation, contributing causation, or something else entirely. Dr. Hill stated that the ISA Preface is not specific in terms of how Dr. Cox outlined causality. Dr. Cox asked whether he thought these distinctions in causality were policy-relevant. Dr. Hill indicated that these distinctions should be taken into account, but that he would not characterize the causal determinations in the ISA and ISA Preface as ambiguous or arbitrary. Dr. Cox asked if the definitions were not ambiguous, whether they singled out a unique meaning for the term "causal." Dr. Hill stated that he did not think they singled out a unique meaning. Dr. Cox agreed and stated that is what he meant by ambiguous. Regarding Dr. Hill's comment of greater evidence exists now for a stronger standard, Dr. Cox asked whether he was referring primarily to new evidence of epidemiological associations at lower concentrations. Dr. Hill indicated that he was. Dr. Cox asked whether he believed that large-scale studies of whether there is a direct statistically significant dependence of mortality on ozone

concentrations provide relevant evidence to whether a stronger standard is needed. Dr. Hill responded that he believed that large-scale studies are important to help guide the standards, that the evidence continues to grow, that a lower standard is more protective of public health, that the CASAC in 2014 made a strong statement in favor of a lower standard level and the evidence since then is even stronger. Dr. Cox asked him whether he was familiar with Vitolo et al. (2018), with almost 50 million records on air pollution, weather variables, and mortality in the United Kingdom. Dr. Hill indicated that he was not familiar with that study.

Vijay Limaye, Natural Resources Defense Council, presented an oral statement⁹ that focused on the failure of the PA to consider the health effects of ozone on outdoor workers; drafting the ISA and PA simultaneously harming the integrity of the process; taking into account the temperature-pollution link; that the scientific literature does not establish a safe ozone level; and that the evidence presented in the ISA and PA indicates that the current ozone standard is not requisite to protect public health with an adequate margin of safety. Regarding Dr. Limaye's comment that there is compelling evidence of significant excess risk even at concentrations below current standards, Dr. Cox asked whether that excess risk is based on population epidemiological associations. Dr. Limaye indicated that was correct. Dr. Cox stated that association-based information does not help answer whether reducing ozone exposures will reduce effects being attributed to ozone and asked whether he was aware of any compelling evidence that does address manipulative causation. Dr. Limaye indicated that they published a commentary in JAMA Internal Medicine two months ago on significant excess risk at levels of 25 ppb and emerging evidence of adverse responses from long term exposures. Dr. Cox indicated that does not address the question of changes, and that only addressed associations between levels of ozone and levels of adverse effects. Dr. Limaye stated that the weight-of-evidence indicates that changes in ozone concentrations over time have contributed to reduced health responses and stated that he would be happy to submit some studies towards that end. Dr. Cox indicated that would be helpful and the sooner he could do so, the more useful it would be.

Brenda Marsh, spoke in Gary Ewart's place, for the American Thoracic Society. She presented an oral statement¹⁰ that focused on the NAAQS review process being rushed, the process suffered from the lack of an Ozone Review Panel, that the consultants were insufficient to replace an Ozone Review Panel, that CASAC should recommend a more protective Ozone NAAQS of 60 ppb, and that they strongly agreed with the CASAC's recommendation to restoring the traditional review process. Regarding her comment that the expertise of the CASAC and consultants was woefully inadequate, Dr. Cox stated that some of CASAC's specific recommendations were that EPA should more fully address how changes in health effects depend on changes in ozone; that they should clarify how studies are selected, weighted, and summarized, and do so systematically; that they should better define the terms used in causal conclusions; that they should further discuss causal biological mechanisms; and that they should present more thorough quantitative uncertainty and sensitivity analyses. He asked whether it was her opinion that the CASAC lacked the specific technical expertise to make and support those specific recommendations. She indicated that it was not her opinion and that she thought those recommendations were well reasoned and thoughtful. He asked whether she thought that the CASAC and non-member consultants together lacked relevant expertise specifically in the parts of epidemiology, that he thought were most relevant, that deal with risk and causation. She stated that she could not answer that question with respect to risk and causation. He asked her if she was familiar with Vitolo et al. (2018). She stated that she was not familiar with that study and asked if he could expound on that study. Dr. Cox stated that there is a particular approach to trying to get at the truth from data, called causal Bayesian networks, and Vitolo et al. applied this approach and found that geographical region plays a strong and confounding role. He stated that they found a significant association between ozone and cardiovascular mortality in

people over 60, and also an association for PM_{2.5}, but that these associations were not direct and could be completely explained by confounding by year, by region, and perhaps other variables.

Discussion of the Draft CASAC Ozone ISA Report

Appendix 10

The CASAC members agreed to add a statement to the end of the second bullet on page 36 referring readers to the “Study Inclusion” and “Biological Plausibility” sections in the consensus responses to the Appendices 3-7 charge questions and individual comments for additional detail about biological information. The CASAC members also agreed to delete the bullet on page 37 regarding Section 10.4 (Peer Review and Public Participation). The CASAC members agreed to add biological causation as an expertise to line 14 and change “ISA development process” to “causal determination process” on line 15 of page 37. On line 19 of page 37, the CASAC members agreed to change the sentence to state that experts from outside the air pollution health effects should be included. The CASAC members also agreed to not be so specific about which Board of the National Academies EPA should work with on line 24 of page 37.

Appendices 1 and 2

The CASAC agreed to revise lines 26-30 on page 7 to not mention the difficulty of reaching the 70 ppb NAAQS and to add that EPA should also discuss ozone design values that can result from U.S. Background (USB).

Appendices 3-7

The CASAC agreed to revise line 37 of page 10 to include other non-causal sources of associations including historical trends, model misspecification, and measurement error. They agreed to revise lines 36-38 on page 17 for clarity. They agreed to revise line 20 of page 19 to include relevant positive and negative key studies when mapping biological plausibility pathways. They agreed to revise lines 25-27 on page 19 to state that there needs to be more discussion of how single perturbations will predispose to chronic disease.

Appendices 8 and 9

On page 36, line 2, the CASAC agreed to delete the phrase “ozone aerosols.”

Executive Summary and Integrative Synthesis

The CASAC agreed to revise lines 37-38 of page 1 to state that it is unclear to what extent the ozone-associated physiological effects represent adverse health effects. On lines 42-43 of page 1, they agreed to revise the sentence to state that it is a crucial scientific topic instead of the most important scientific topic. For the sentence on lines 1-2 on page 2, the CASAC agreed to revisions for clarity. For lines 19-21 on page 2, the CASAC agreed to strike the term “realistic” and remove the mention of decrements in lung function. On line 17 of page 2, the CASAC agreed to add population, exercise, and other differences as possible confounders.

On line 7, page 3, the CASAC agreed to revise the sentence to state that the ISA does not provide a complete and accurate summary of studies that it cites. On lines 28-31 on page 3, the CASAC agreed to

add a statement that the non-significant finding in Moore et al. (2012) may have been due to reduced power and to clarify that the authors did not revise their paper, but came to a different conclusion. The CASAC agreed to strike lines 36 of page 3 through line 15, on page 4, and to strike lines 21-26 on page 4. On line 27 on page 4, the CASAC agreed to revise the first sentence to state that the science related to possible health benefits of reducing ozone needs to be more fully addressed. The CASAC agreed to strike lines 37 on page 4 through line 13 on page 5.

Discussion of Letter to the Administrator

On lines 16-28 of page 2 of the letter, the CASAC agreed to revise the language to be consistent with the language used in the consensus responses. On line 32 of page 1 of the letter, the CASAC agreed to add a new paragraph on overarching process issues, using similar language from the Draft CASAC report on the Ozone PA.

Disposition of the Draft CASAC Ozone ISA Report

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

The meeting was recessed at 4:00 pm.

Wednesday, February 12, 2020

Discussion of the Draft CASAM Ozone PA Report

Chapter 1 and Chapter 2

The CASAC agreed to revisions to lines 32-39 of page 1 to recommend that the causal determination framework be reevaluated with the goal of improving clarity and reducing ambiguity, and to point to non-CASAC member consultant comments on the causal determination framework in Appendix B of the CASAC Ozone ISA Report. The CASAC members also agreed to using similar language as the CASAC Ozone ISA Report regarding the recommendation for EPA to work with outside experts and the National Academies in revising and improving the causal determination framework.

The CASAC agreed to delete item (d) on lines 18-19 on page 2 and to revising lines 22-39 on page 2 to use similar language from the CASAC PM PA Report. The CASAC agreed to clarify that the systematic review should be done in the ISA and summarized and referenced in the PA on line 8 of page 31. For lines 12-14 on page 3, the CASAC agreed with revisions for the PA to define and caveat regression C-R functions appropriately. For lines 15-18 on page 2, the CASAC agreed to delete “preventable by reducing current ozone levels” and “persistent.” On page 3, line 37, the CASAC agreed to add intrastate and interstate ozone transport.

Chapter 3 and Chapter 4

On page 8, lines 20-22, the CASAC agreed to revisions to clarify the need for EPA to distinguish and discuss separately the potential for people with asthma to experience greater effects and their responses caused by diminished reserve. They agreed to delete lines 22-28 on page 8. They also agreed to revisions for clarity on the buffer sites on page 12, lines 21-22 and line 30.

The CASAC agreed to move the Future Research section to after the consensus response on Chapter 4 and to add a recommendation for future research into the form of the ozone standard with specific focus on moving from the fourth-highest daily maximum 8-hour ozone concentrations to a more integrated approach (e.g. average of 10 highest daily maximum 8-hour ozone average concentrations). They also agreed to recommend further research into new technology to inform exposures of the general population, including sensitive/at-risk populations, to ozone.

Discussion of Letter to the Administrator

The CASAC agreed to revise the Letter to reflect the revisions agreed upon in the consensus responses. The CASAC agreed to revise lines 41 of page 1 of the letter to line 1 of page 2 to reflect that some members of CASAC agreed with the previous CASAC’s findings and recommendations in their review of the 2014 Second Draft Ozone PA that opined that a primary standard set at 70 ppb may not be protective of public health with an adequate margin of safety.

Disposition of the Draft CASAC Ozone PA Report

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

The meeting was adjourned by Mr. Yeow at 2:45 pm.

Respectfully Submitted:

Certified as Accurate:

/s/

/s/

March 9, 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 February 11-12, 2020, meeting webpage: <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/CDB2E140F088220F852584E6006CDB44?OpenDocument>

¹ 01-21-2020 Draft CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft)

² 01-21-2020 Draft CASAC Review of the EPA's Policy Assessment for the Review of the Ozone NAAQS (External Review Draft)

³ Chartered CASAC Roster

⁴ Federal Register Notice Announcing the Meeting

⁵ Agenda

⁶ List of Registered Public Speakers

⁷ Oral Statement from Julie Goodman, Gradient

⁸ Oral Statement from David G. Hill, American Lung Association

⁹ Oral Statement from Vijay Limaye, Natural Resources Defense Council

¹⁰ Oral Statement from Brenda Marsh, American Thoracic Society

ATTACHMENT A – Other Attendees

Name	Affiliation
Allen, George	
Anderson, Craig	California Air Resources Board
Baca, Michael	New Mexico Environment Department
Bahadori, Tina	USEPA
Barber, Kathy	Caterpillar
Benromdhane, Souad	USEPA
Billings, Paul	American Lung Association
Brimmer, Amanda	Denver Regional Air Quality Council
Buckley, Barbara	USEPA
Chan, Elizabeth	USEPA
Clark, David	ADEQ
Cooper, Czarina	USEPA
Copley, Bruce	ExxonMobil Biomedical Sciences, Inc.
Davidson, Ken	USEPA
Dolwick, Pat	USEPA
Downs, Tom	
Ewart, Gary	American Thoracic Society
Feld, Jodi	New York State Office of the Attorney General
French, Timothy A.	Truck and Engine Manufacturers Association
Frey, H. Christopher	North Carolina State University
Goldman, Gretchen	Union of Concerned Scientists
Goodman, Julie	Gradient
Graham, John	Clean Air Task Force
Graham, Stephen	USEPA
Guillen, Alex	Politico
Harlan, Matt	
Hassan, Iman	USEPA
Henderson, Barron	USEPA
Herrick, Jeff	USEPA
Hill, David	American Lung Association
Hines, Erin	USEPA
Hoekzema, Andrew	Capital Area Council of Governments
Hornback, John	Metro 4/SASARM
Hotchkiss, Andrew	USEPA
Hutson, Mary	USEPA
Jacobs, Wendy	CT DEEP
Jerry, Roger	SC Dept of Health and Environmental Control
Kadlec, Matt	WA Dept of Ecology

Name	Affiliation
Kamal, Ali	USEPA
Kirrane, Ellen	USEPA
Knoll, Kris	TxDOT
Langstaff, John	USEPA
Langworthy, Lucinda	Hunton Andrew Kurth LLP
Lassiter, Meredith	USEPA
Lefohn, Allen S.	A.S.L. & Associates
Limaye, Vijay	Natural Resources Defense Council
Lloyd, Christine	USEPA
Lo, Edward	Association of Schools and Programs of Public Health
Luben, Tom	USEPA
Madden, Glenda	SC Dept of Health and Environmental Control
Marsh, Brenda	American Thoracic Society
McDow, Steve	USEPA
Miyasato, Lori	California Air Resources Board
Mudasiru, Omobola	American Petroleum Institute
Paige, Carrie	USEPA Region 6
Parker, Stuart	IWP News
Peppers, Melissa	USEPA
Plautz, Jason	Media
Popovech, Marusia	ExxonMobil Biomedical Sciences, Inc.
Puett, Harley	City of San Antonio Office of Sustainability
Reyes, Jeanette	USEPA
Rice, Richard	USEPA
Rives, Glenn	
Roger, Jerry	SC Dept of Health and Environmental Control
Russo, Andrew	Illinois EPA
Sack, Jason	USEPA
Sales, Hillarie	Oregon DEQ
Sauerhage, Maggie	USEPA
Sax, Sonja	Ramboll
Sharma, Rohit	Lyondell Chemical Company
Simmons, Jane Ellen	USEPA
Slattery, Karen	RIDEM Office of Air Resources
Steichen, Ted	American Petroleum Institute
Stewart, Michael	USEPA
Thomas, Stephanie	Public Citizen
Thompson, Lisa	USEPA
Underhill, Jeff	NHDES / OTC
Valles, Claudia	El Paso Metropolitan Planning Organization

Name	Affiliation
Wajda-Griffin, Scott	NYS Dept of Environmental Conservation
Wayland, Robert	USEPA
Weaver, Chris	USEPA
Weitekampe, Chelsea	USEPA
Wells, Ben	USEPA
Wesson, Karen	USEPA
Whiteman, Chad	U.S. Chamber of Commerce
Wickersham, Denise Rayborn	Consultant - Energy, Environment & Sustainability
Williams, Melina	USEPA
Zarba, Chris	