

**Summary Minutes of the  
U.S. Environmental Protection Agency (EPA)  
Clean Air Scientific Advisory Committee (CASAC)  
Oxides of Nitrogen Review Panel  
Public Meeting  
June 2-3, 2015**

Date and Time: Tuesday, June 2, 2015, 9:00 AM – 5:00 PM ET;  
Wednesday, June 3, 2015, 8:00 AM – 3:30 PM ET

Location: Doubletree Raleigh Brownstone-University Hotel, 1707 Hillsborough St, Raleigh, NC 27605

Purpose: The purpose of the meeting was to peer review EPA's *Integrated Science Assessment (ISA) for Oxides of Nitrogen - Health Criteria (Second External Review Draft – January 2015)* and *Risk and Exposure Assessment Planning Document (External Review Draft)*.

Participants: CASAC Oxides of Nitrogen Review Panel (for full Panel, see roster<sup>1</sup>)

Dr. H. Christopher Frey, Chair  
Mr. George A. Allen  
Dr. Matthew Campen  
Dr. Ronald Cohen  
Dr. Douglas Dockery  
Dr. Philip Fine  
Dr. Panos Georgopoulos (by phone)  
Dr. Jack Harkema  
Dr. Michael Jerrett  
Dr. Joel Kaufman  
Dr. Michael Kleinman (by phone)  
Dr. Timothy Larson (by phone)  
Dr. Jeremy Sarnat  
Dr. Lianne Sheppard (by phone)  
Dr. Helen Suh (by phone)  
Dr. Ronald Wyzga

Mr. Aaron Yeow, Designated Federal Office (DFO)  
Mr. Christopher Zarba, EPA SAB Staff Office  
Dr. John Vandenberg, EPA National Center for Environmental Assessment (NCEA)  
Dr. Molini Patel, EPA NCEA  
Dr. Erika Sasser, EPA Office of Air Quality and Planning Standards (OAQPS)  
Dr. Scott Jenkins, EPA OAQPS  
Dr. Stephen Graham, EPA OAQPS  
Dr. Zachary Pekar, EPA OAQPS  
Other Attendees (See Attachment A)

**Tuesday, June 2, 2015**

## **Opening Remarks**

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 the meeting minutes will be made publicly available after the meeting. He noted that there were two public comment periods noted on the agenda for members of the public who registered in advance with the SAB Staff Office to make oral comments. He stated that there were also two clarifying comment periods on the agenda where members of the public could request an opportunity to provide short clarifying comments. He noted that the Panel received several written public comments, which were also 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 Panel members. He then turned the meeting over to Mr. Christopher Zarba, Director of the SAB Staff Office, who welcomed everyone, and then turned it over to Dr. H. Christopher Frey, Chair of the CASAC.

Dr. Frey welcomed everyone and had the Panel members introduce themselves. He then provided an overview of the Agenda.<sup>3</sup>

## **EPA Presentation on ISA**

Dr. John Vandenberg, EPA NCEA, made a presentation<sup>4</sup> to the Panel, introducing the ISA for Oxides of Nitrogen team, and providing the timeline for the ISA. Dr. Molini Patel continued the presentation, summarizing overarching recommendations from CASAC on the 1<sup>st</sup> Draft ISA and outlining the major revisions made based on CASAC's recommendations.

## **Public Comments on the ISA**

Deborah Shprentz, Consultant to the American Lung Association, presented comments<sup>5</sup> on the ISA which focused on the American Lung Association concurring with EPA's conclusion that short-term exposures to NO<sub>2</sub> cause adverse respiratory effects and that they are particularly concerned about the impact of brief exposures to NO<sub>2</sub> on people with asthma. She also referenced the World Health Organization's recently completed technical review of recent scientific evidence on the health effects of various air pollutants that found support for updating the current WHO air quality guidelines for NO<sub>2</sub>. The current EPA hourly standards for NO<sub>2</sub> are roughly equivalent to the WHO guideline values, but the annual average standards are well above the WHO guidelines.

Kirsten Zu, Gradient, presented comments<sup>6</sup> on behalf of the American Petroleum Institute, which focused on problems with the application of the causal framework, assessment of individual studies, lack of consistency and coherence in the available data, uncertainties regarding the independent effects of NO<sub>2</sub>, and the ISA not providing sufficient evidence to support the strengthening of any causal determination.

## **Discussion of the ISA Charge Questions and Response to ISA Charge Questions**

### *Chapter 2 – Atmospheric Chemistry and Ambient Concentrations of Oxides of Nitrogen*

The Panel found the 2<sup>nd</sup> Draft ISA to be much improved and responsive to the CASAC's prior comments on the 1<sup>st</sup> Draft ISA. There was a discussion of national scale variability, the coefficient of divergence, near road gradients, limitations in the studies in Table 2-6, the need for the most up-to-date near-road monitoring data, data on explanatory variables such as traffic and land-use, long term trends, the London near-road monitoring data, and recent initiation of Canadian roadside measurements.

### *Chapter 3 – Exposure to Oxides of Nitrogen*

The Panel appreciated the responsiveness to the prior CASAC comments and the separation of exposure into its own chapter. There was discussion about the causal determination for respiratory effects associated with short-term NO<sub>2</sub> exposures. The change in the causal determination is appropriately driven by interpretation of controlled exposure studies. The epidemiology studies were not able to separate respiratory effects associated with NO<sub>2</sub> from copollutants and traffic mixtures and do not support the strengthening of the causal determination. Therefore, the Panel recommended that the document clarify that the strengthening of the causal determination for respiratory effects associated with short-term NO<sub>2</sub> exposures is driven by controlled human exposure studies, not epidemiology studies. The Panel discussed several related issues, including the role of multiple pollutants with respect to oxidative stress, and the need for a more complete conceptual exposure framework to account for significant exposure factors, such as activity levels.

### *Chapter 4 – Dosimetry and Modes of Action for Oxides of Nitrogen*

The Panel found the chapter to be stronger, better organized, and had better flow. The document was clearer with regards to the limitations and uncertainties associated with the NO<sub>2</sub> dosimetry models. The chapter appropriately reflects the current state of knowledge. They found the mode of action figures to be useful but discussed several possible modifications aimed at improved accuracy and clarity.

### *Chapters 5 and 6 – Integrated Health Effects of Short-Term and Long-Term Exposure to Oxides of Nitrogen*

The Panel thought that the revised chapter was an improvement and integrated well the evidence across disciplines. They were particularly impressed with the meta-analysis of controlled human exposure studies. They thought that there should be more discussion about the possibility of surrogacy and how examination of the available data could aid in inferences about NO<sub>2</sub> health effects. Copollutants were generally well addressed, but the Panel thought that there should be greater distinction between copollutants of greater concern and those of lesser concern. There was some discussion on the evaluation criteria for studies. The Panel indicated that a better rationale should be provided for the changes in some of the causal determinations.

### *Chapter 7 – Populations and Lifestages Potentially at Increased Risk for Health Effects Related to Nitrogen Dioxide Exposure*

The Panel found the chapter to be an improvement over the previous version and the conclusions in the chapter are sound and well-justified. The Panel noted some areas for improvement such as a better

discussion of effect modification and noted some conflation between individual-level and group-level socioeconomic status.

### *Executive Summary and Chapter 1 – Integrative Synthesis*

The Panel found the Executive Summary and Chapter 1 to be improved, with less technical jargon, and less redundancy. The Panel recommended increased conciseness and that more clarification and justification for causal determination changes be provided.

The lead authors then summarized the key points and findings from each of their charge questions.

### **Public Clarifying Comments**

There were no public clarifying comments on the ISA or the Panel's deliberations.

The meeting was recessed for the day at 4:45 pm.

### **Wednesday, June 3, 2015**

The Panel was reconvened at 8:00 am.

### **EPA Presentation on the REA Planning Document**

Dr. Erika Sasser, EPA OAQPS, made a presentation<sup>7</sup> to the Panel, which focused on an overview of the review process for the NO<sub>2</sub> Primary NAAQS and tentative schedule for the current review of the Primary NO<sub>2</sub> NAAQS. She indicated that the agency will be focusing on quantitative analyses that will either feed into a standalone risk and exposure assessment or folded into the policy assessment. Dr. Scott Jenkins continued the presentation and focused on an overview of the planning document, the history of the Primary NO<sub>2</sub> NAAQS, an overview of the NAAQS risk characterization approaches, and an overview of the decision framework. Dr. Stephen Graham continued the presentation, focusing on the air quality and health benchmark comparison from the last review, in the current review, new information from near-road monitors, study area selection, air quality adjustment, on-road simulation, example study area and preliminary results, next steps for air quality and health benchmark comparisons, human exposure assessment from the last review and current review. Dr. Zachary Pekar continued the presentation and focused on risk assessment based on controlled human exposure studies and based on epidemiology studies.

### **Public Comments on the REA Planning Document**

Dr. Kirsten Zu, Gradient, presented comments<sup>8</sup> on behalf of the American Petroleum Institute, which focused on why a new air quality analysis should be conducted, why a new exposure assessment should not be conducted, and why the 2008 REA was overly conservative and should not be used to judge the adequacy of the current standard.

## **Discussion of the REA Planning Document Charge Questions and Response to Charge Questions**

### *Chapter 1 – Introduction*

The Panel found that Chapter 1 of the REA Planning Document provides a clear introduction, background information, and good perspective of the role of the REA Planning Document in the NAAQS review.

### *Chapter 2 – Air Quality and Health Benchmark Comparisons*

The Panel found the information in Chapter 2 to be clear. However, more explanation about the approach to making adjustments of ambient concentrations to “just meet” the standard should be provided at the beginning of the chapter. The chapter identifies the most important and relevant information available to inform updated analyses of ambient NO<sub>2</sub> concentrations, but would benefit from considering and including additional information on available traffic counts, fleet mix data, historical emissions information and trends. There was discussion about the need for the most up-to-date near-road monitoring data. They found the choice of benchmarks for the 1-hour NO<sub>2</sub> standard supported by the information in the ISA and thought that the lower short-term exposure concentration benchmarks (100 ppb) should be emphasized. The Panel concurred with EPA staff’s approach for selecting urban study areas, but recommends consideration of additional factors related to emission source strength and proximity. The Panel discussed and formulated recommendations for making inferences about uncertainty with respect to the air quality adjustment approach.

### *Chapter 3 – Exposure Assessment*

The Panel was generally supportive of the model-based exposure assessment in the REA Planning Document. They recommended examining the use of a hybrid or blended approach that integrates across chemical transport models, land use regression, and ambient monitoring data to address uncertainties in AERMOD. The Panel expressed strong preference for the application of quantitative uncertainty analysis.

### *Chapter 4 – Human Health Risk Assessment*

The Panel generally agreed with the EPA’s conclusion that a quantitative risk assessment based on the controlled human exposure studies is not warranted at this time. There was some discussion about the margin of safety, but Dr. Frey indicated that this would be taken up in the Policy Assessment.

The Panel agreed with the EPA that a quantitative risk assessment based on the epidemiological data on short-term exposures was not warranted at this time. For long-term NO<sub>2</sub> exposures, there was discussion about moving forward with a quantitative risk assessment based on epidemiology studies of asthma, but the Panel recognized the difficulty of separating the independent effects of NO<sub>2</sub> versus copollutants. Dr. Jerrett indicated that one key study seemed to be missing, the McConnell et al. (2010) study, of which he was a coauthor, and that study did produce copollutants estimates. Other Panel members cautioned that the risk estimates have to be scientifically defensible and the copollutant issue would make producing credible estimates difficult.

Mr. Yeow announced that because Dr. Jerrett was a coauthor of the McConnell et al. (2010) study, he is recusing himself from any discussions regarding the use and appropriateness of the study. He is, however, available to answer clarifying questions regarding the study.

After further examination of the McConnell study, the Panel did not think that it alone would sufficiently address the issue of copollutants. After further discussion, the Panel agreed to recommend that the EPA examine the feasibility of performing a quantitative risk assessment based on the totality of the epidemiology evidence of the long-term NO<sub>2</sub> exposures.

*Overarching Question*

Dr. Frey indicated that the overarching question was meant to be a catchall in case the Panel had additional views and thoughts regarding the approach that were not captured in the other charge questions. There was some discussion about mixtures and multipollutant approaches. The Panel concluded that this was beyond the scope of the REA Planning Document. Dr. Frey indicated that these items, and other “big picture” items arising during the course of the review, could go into the letter for the Policy Assessment.

**Public Clarifying Comments on the REA Planning Document**

There were no public clarifying comments.

**Summary and Action Items**

Dr. Frey discussed action items and the remaining schedule for drafting the reports.

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

Respectfully Submitted:

Certified as Accurate:

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Mr. Aaron Yeow  
Designated Federal Officer  
EPA SAB Staff Office

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Dr. H. Christopher Frey  
Chair  
CASAC Oxides of Nitrogen Review Panel

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: <http://www.epa.gov/casac>, at the [June 2-3, 2015 CASAC Oxides of Nitrogen Review Panel Meeting page](#):

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<sup>1</sup> CASAC Oxides of Nitrogen Review Panel Roster

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

<sup>3</sup> Agenda

<sup>4</sup> EPA Presentation - Main Revisions to Draft Integrated Science Assessment (ISA) for Oxides of Nitrogen - Health Criteria

<sup>5</sup> Oral Statement on the ISA from Deborah Shprentz, Consultant to the American Lung Association

<sup>6</sup> Presentation on the ISA by Ke Zu, Gradient, on behalf of the American Petroleum Institute

<sup>7</sup> EPA Presentation - National Ambient Air Quality Standards (NAAQS): NO<sub>2</sub> REA Planning Document (updated 06-02-15)

<sup>8</sup> Oral Statement on the REA Planning Document from Kirsten Zu, Gradient, on behalf of the American Petroleum Institute

**ATTACHMENT A – Other Attendees**  
**CASAC Oxides of Nitrogen Review Panel Public Meeting**

Name	Affiliation	Tuesday, June 2, 2015	Wednesday, June 3, 2015
Alman, Breanna	EPA	X	X
Brown, James	EPA	X	
Chen, Elizabeth	EPA		X
Coffman, Evan	EPA	X	
Davis, Matthew	EPA	X	
Ethridge, Shannon*	Texas Commission for Environmental Quality	X	X
Hines, Erin	EPA	X	
Hubbell, Bryan	EPA	X	X
Jansen, John J.	Southern Company	X	X
Kertes, Noella*	CQ-Roll Call	X	X
Kirrane, Ellen	EPA	X	
Kwong, Jeanette*	California Air Resource Board	X	X
Lamson, Amy	EPA	X	X
Langworthy, Cindy	Hunton & Williams	X	X
Luben, Tom	EPA	X	
McDow, Steve	EPA	X	
Naess, Liz	EPA		X
Nichols, Jennifer	EPA	X	
Nyberg, Carina*	ASC Services LLC	X	X
Oakes, Michelle	EPA	X	
Ollison, Will*	American Petroleum Institute	X	X
Owen, Chris	EPA		X
Parker, Stuart*	Inside EPA	X	X
Pinto, Joe	EPA	X	
Poparech, Marusia	Exxon Mobil	X	X
Rappazzo, Kristen	EPA	X	
Richmond-Bryant, Jennifer	EPA	X	X
Sacks, Jason	EPA	X	
Shprentz, Deborah*	Consultant to the American Lung Association	X	X
Steichen, Ted	American Petroleum Institute	X	X
Stevens, Tina	EPA	X	
Walsh, Debra	EPA	X	X
Watkins, Nealson	EPA	X	X
Wesson, Karen	EPA	X	
Williams, M.	EPA	X	X
Zu, Kirsten	Gradient	X	

\*participated via telephone