

**U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee (CASAC)
CASAC Ozone Review Panel**

Summary Meeting Minutes of the CASAC's Public Advisory Teleconference

Friday, March 28, 2008 – 1:00 to 4:00 p.m. Eastern Time

SAB Staff Office, Washington DC

Advisory Meeting to Hold Follow-on Discussions Concerning EPA's Final Rule for the National Ambient Air Quality Standards (NAAQS) for Ozone

Panel Members: See CASAC Ozone Review Panel Roster – Appendix A

Agenda: See Meeting Agenda – Appendix B

Purpose: The purpose of this public teleconference meeting was for the CASAC Ozone Review Panel to hold follow-on discussions concerning the Final Rule for the National Ambient Air Quality Standards (NAAQS) for ozone.

Attendees:

| | |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chair: | Dr. Rogene Henderson |
| CASAC Members: | Dr. Ellis Cowling Dr. James Crapo Dr. Douglas Crawford-Brown Dr. Donna Kenski Dr. Armistead (Ted) Russell |
| Panel Members: | Dr. John Balmes Dr. William (Jim) Gauderman Dr. Paul Hanson Dr. Philip Hopke Dr. Allan Legge Dr. Morton Lippmann Dr. Frederick Miller Dr. Maria Morandi Dr. Charles Plopper Mr. Richard Poirot Dr. Elizabeth (Lianne) Sheppard Dr. Frank Speizer Dr. James Ultman Dr. Sverre Vedal Dr. James Zidek Dr. Barbara Zielinska |
| EPA SAB Staff: | Mr. Fred Butterfield, CASAC DFO Dr. Vanessa Vu, SAB Staff Office Director |

Other EPA Staff: Dr. Jeff Arnold, ORD, NCEA-RTP
Dr. James Brown, ORD, NCEA-RTP
Dr. Barbara Buckley, ORD, NCEA-RTP
Dr. Ila Cote, ORD, NCEA-RTP
Mr. Jeffrey Herrick, ORD, NCEA-RTP
Dr. Jee Young Kim, ORD, NCEA-RTP
Dr. John Langstaff, OAR, OAQPS
Dr. Karen Martin, OAR, OAQPS
Dr. Dave McKee, OAR, OAQPS
Dr. Joe Pinto, ORD, NCEA-RTP
Mr. Harvey Richmond, OAR, OAQPS
Dr. Mary Ross, ORD, NCEA-RTP
Ms. Vicki Sandiford, OAR, OAQPS
Ms. Susan Stone, OAR, OAQPS
Ms. Debra Walsh, ORD, NCEA-RTP
Dr. William Wilson, ORD, NCEA-RTP

Meeting Summary

The discussion followed the issues and general timing as presented in the meeting agenda (Appendix B).

Convene Meeting, Call Attendance, Introduction and Administration

Mr. Fred Butterfield, Designated Federal Officer (DFO) for the Clean Air Scientific Advisory Committee, opened the teleconference meeting, called attendance, and welcomed all attendees. He noted the CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA) to provide advice and recommendations to the EPA Administrator. Consistent with FACA regulations, the deliberations of CASAC are held as public meetings and teleconferences for which advance notice is given in the *Federal Register*. The DFO is present at all such meetings to assure compliance with FACA requirements. He mentioned that there would be three individuals making public comments today. Mr. Butterfield said a transcript of this teleconference is not being taken. However, summary minutes were taken (by the DFO) for this teleconference meeting. These minutes will be certified by the CASAC (and Ozone Review Panel) Chair and posted on the SAB Web Site (<http://www.epa.gov/casac>) within 90 days after this meeting. Mr. Butterfield noted that all panelists had earlier submitted documentation with respect to possible financial conflicts-of-interest or appearances of a lack of impartiality, which was reviewed by the SAB staff prior to the teleconference meeting and found to be satisfactory.

Purpose of Meeting and Welcome

Dr. Rogene Henderson, CASAC and Ozone Review Panel Chair, welcomed Panel members and briefly stated the purpose of the meeting (see above). Dr. Henderson emphasized that the purpose of any additional, unsolicited advice that the CASAC would provide the EPA Administrator was to inform the Agency's future deliberations during the next review cycle for the NAAQS for ozone that will begin next year.

Public Comment Period

Mr. Butterfield, CASAC DFO, facilitated the formal public comment period. Three members of the public had signed-up in advance to offer oral public comments, but only two individuals were available to speak on the teleconference, as follows:

- Mr. Deborah Shprentz, consultant to the American Lung Association
- Dr. Roger McClellan, independent consultant

The speakers' public statements are attached in Appendix C. The public comment period included a brief question-and-answer exchange between speakers and members of the Panel.

Summary of the CASAC Ozone Review Panel's Discussions Concerning EPA's Final Rule for the Ozone NAAQS

The members of the CASAC Ozone Review Panel expressed their general disappointment with the primary (public health-based) and secondary (welfare-based) National Ambient Air Quality Standards for ozone that EPA announced on March 12, 2008 — and, in particular, that the primary NAAQS did not provide adequate margin of safety for public health, as is required by the Clean Air Act; and that the Agency did not issue a separate secondary standard that was different in form, indicator and level, *i.e.*, one that was more biologically-relevant, than the primary ozone standard.

After this brief introductory discussion, the remainder of the teleconference (approximately two hours) consisted of an interactive discussion and an “editing session” focusing on the working-draft letter to the Administrator that had been prepared by the Chair and posted on the SAB Web Site (<http://www.epa.gov/casac>). Dr. Henderson led Ozone Panel members sequentially through the various sections of the letter, and Mr. Butterfield (acting in the capacity as a secretary for the advisory body) incorporated Panelists' comments that were either given verbally on the teleconference line or sent to him “real-time” via e-mail.

At the conclusion of this process, and prior to adjournment, the Chair canvassed the members of the Ozone Panel — and especially the five other members of the statutory (chartered) Clean Air Scientific Advisory Committee who were also on the conference call — to ensure that Panel members were in substantial agreement with (*i.e.*, approved) the language in the letter, pending members' final review and individual concurrence subsequent to the meeting.

Summary and Next Steps

Dr. Henderson thanked the members of the Ozone Panel and asked that Panel members provide both her and Mr. Butterfield with their concurrence or review/concurrence comments on a concurrence draft of the CASAC's letter — to be sent-out later that afternoon — by no later than the close of business on the following Tuesday, April 1. The Chair and the DFO will then work toward sending a proposed final draft letter to the members of the Ozone Panel by the following day, April 2 — and would be requesting essentially a 24-hour turnaround for any final comments, with a goal of being able to transmit this final letter to the EPA Administrator by that next Friday, April 4.

The DFO adjourned the meeting at approximately 3:40 p.m.

Respectfully Submitted:

Certified as True:

/s/

/s/

Fred A. Butterfield, III

Rogene F. Henderson, Ph.D.

Fred A. Butterfield, III
CASAC DFO

Rogene F. Henderson, Ph.D.
CASAC Chair

Date: April 15, 2008

Appendix A – Roster of the CASAC Ozone Review Panel

U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office Clean Air Scientific Advisory Committee (CASAC) CASAC Ozone Review Panel

CASAC MEMBERS

Dr. Rogene Henderson (Chair), Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Ellis Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James D. Crapo [M.D.], Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown,[§] Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. Donna Kenski,[†] Director of Data Analysis, Lake Michigan Air Directors Consortium (LADCO), Rosemont, IL

Dr. Armistead (Ted) Russell,[§] Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Jonathan Samet [M.D.],[†] Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

PANEL MEMBERS

Dr. John Balmes, Professor, Department of Medicine, University of California San Francisco, University of California – San Francisco, San Francisco, California

Dr. William (Jim) Gauderman, Professor, Department of Preventive Medicine, School of Medicine, University of Southern California, Los Angeles, CA

Dr. Paul J. Hanson, Senior Research and Development Scientist, Environmental Sciences Division, Oak Ridge National Laboratory (ORNL), Oak Ridge, TN

Dr. Jack Harkema,* Professor, Department of Pathobiology, College of Veterinary Medicine, Michigan State University, East Lansing, MI

Dr. Philip Hopke, Bayard D. Clarkson Distinguished Professor, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Dr. Michael T. Kleinman, Professor, Department of Community & Environmental Medicine, University of California – Irvine, Irvine, CA

Dr. Allan Legge, President, Biosphere Solutions, Calgary, Alberta, Canada

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. Frederick J. Miller, Consultant, Cary, NC

Dr. Maria Morandi, Assistant Professor of Environmental Science & Occupational Health, Department of Environmental Sciences, School of Public Health, University of Texas – Houston Health Science Center, Houston, TX

Dr. Charles Plopper, Professor, Department of Anatomy, Physiology and Cell Biology, School of Veterinary Medicine, University of California – Davis, Davis, California

Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Elizabeth A. (Lianne) Sheppard, Research Professor, Biostatistics and Environmental & Occupational Health Sciences, Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. James Ultman, Professor, Chemical Engineering, Bioengineering Program, Pennsylvania State University, University Park, PA

Dr. Sverre Vedal, Professor of Medicine, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. James (Jim) Zidek, Professor, Statistics, Science, University of British Columbia, Vancouver, BC, Canada

Dr. Barbara Zielinska, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

SCIENCE ADVISORY BOARD STAFF

Mr. Fred Butterfield, CASAC Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC, 20460, Phone: 202-343-9994, Fax: 202-233-0643 (butterfield.fred@epa.gov)

[§]Dr. Crawford-Brown was appointed to the Clean Air Scientific Advisory Committee in October 2006; Dr. Russell was a member of the CASAC Ozone Review Panel and was appointed to the Clean Air Scientific Advisory Committee in October 2006.

[†]Dr. Kenski and Dr. Samet were appointed to the Clean Air Scientific Advisory Committee in October 2007.

*Dr. Harkema did not participate in this current CASAC Ozone Review Panel activity.

Appendix B – Meeting Agenda

**U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee (CASAC)
CASAC Ozone Matter Review Panel**

Public Teleconference Meeting

Friday, March 28, 2008 – 1:00 to 4:00 p.m. Eastern Time

Advisory Meeting to Hold Follow-on Discussions Concerning EPA’s Final Rule for the National Ambient Air Quality Standards (NAAQS) for Ozone

Meeting Agenda

| | | |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| 1:00 p.m. | Convene Teleconference; Call Attendance; Introductions and Administration | Mr. Fred Butterfield, CASAC DFO |
| 1:10 p.m. | Purpose of Meeting | Dr. Rogene Henderson, Chair |
| 1:15 p.m. | Public Comment Period | Mr. Butterfield (Facilitator) |
| 1:45 p.m. | Panel Members’ Discussions | CASAC Ozone Review Panel |
| | <u>Discussion Topic</u> | |
| | <ul style="list-style-type: none"> • Public health-based (primary) O₃ NAAQS • Welfare-based (secondary) O₃ NAAQS • CASAC’s preliminary working draft letter to the EPA Administrator concerning the Final Rule on Ozone NAAQS | |
| 3:45 p.m. | Summary and Next Steps | Dr. Henderson |
| 4:00 p.m. | Adjourn Meeting | Mr. Butterfield |

Appendix C – Public Speakers' Comments

Mr. Deborah Shprentz, Consultant to the American Lung Association

Remarks for CASAC Teleconference March 28, 2008

This is Deborah Shprentz. I am a consultant to the American Lung Association. I'd like to commend this Committee for its persistence and diligence in holding EPA's feet to the fire by conducting this review of the final revisions to the National Ambient Air Quality Standards (NAAQS) for ozone.

Having reviewed hundreds of pages of the preamble and the response to comments, I am left wanting as to the rationale for departing from the strong, unequivocal, scientific consensus on the appropriate range for a primary standard, as unanimously recommended by CASAC. I am left wondering which safety factors have been incorporated in reaching a final decision.

The final standard, while an improvement, falls far short of the requirements of the Clean Air Act to protect public health with an adequate margin of safety to protect sensitive populations.

Given all that has transpired, we find the Committee's draft letter a bit tepid in its response.

We were also very troubled by the Administrator's call for legislative changes to the Clean Air Act's NAAQS standard-setting provisions.

Americans have a right to know if the air they breathe is safe or not. Then need clear, unbiased, health-based National Ambient Air Quality Standards that are unalloyed by cost, risk, or other considerations.

The great value of the current approach is that the air quality standards, the goals, are strictly science-based. Some groups contend that the air quality standards should be based on cost to them, rather than on avoiding injury to breathers. There are obvious equity flaws with this approach, not to mention great analytical uncertainties. For instance, historically, cost estimates have proven to be wildly off the mark. The practice of benefits assessment is in its infancy.

The Administrator's principles seem to suggest that costs, risks, and feasibility be considered when setting the standards — the goals that define when the air is safe to breathe.

Such an approach would tamper with the essential purpose of the Clean Air Act: the protection of human health.

The principles further suggest abandoning the requirement for prompt and regular reviews of the science to assess whether revisions to the standards are needed to protect public health. The five year review cycle is essential to ensure that the standards are based on current information. The present Clean Air Act allows ample opportunity for cost, feasibility, timelines and other considerations to be taken into account — during the implementation phases.

The Clean Air Act has been extremely effective in driving down emissions of air pollution,

while accommodating economic growth. Its technology forcing provisions have been a great success story. The air quality standards are central to this process.

We urge this committee to continue to hold EPA accountable for its final decisions on the ozone NAAQS.

Dr. Roger McClellan, Independent Consultant

How Low is Low Enough for the Ozone Standard?

Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis
13701 Quaking Aspen Place N.E.
Albuquerque, NM 87111-7168
Tel: 505-296-7083
E-mail: roger.o.mcclellan@att.net

Prepared for
March 28, 2008 Teleconference
USEPA Clean Air Scientific Advisory Committee Ozone Panel

Good afternoon, I am Roger O. McClellan, an independent consultant on inhalation toxicology and risk analysis issues. The comments I offer today are based on my previous service as Chair of the Clean Air Scientific Advisory Committee (CASAC) and service on numerous CASAC Panels dealing with ozone and other criteria air pollutants.

This afternoon I would like to comment on the role of science and judgment in the “Final Rule for the National Ambient Air Quality Standard for Ozone” announced by EPA Administrator Stephen Johnson. This Final Rule revises the 1997 Standard and concludes a process begun in September 2000. As required by a Court Decree, the EPA published a Proposed Rule on July 11, 2007 and requested public comments on anticipated action in issuing a Final Rule for the ozone standard. Numerous comments were submitted to the official ozone docket. I personally submitted comments¹ to the ozone docket and also joined with 9 of my scientific colleagues in submitting a document² – “Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone” to the docket. Since release of the Proposed Rule, there has been continued debate over the Final Rule that was just issued. That discussion continues even today as evidenced by this meeting.

Much of the discussion has focused on the science that informs the policy judgments that must be made in setting the NAAQS for ozone. The discussion has included repeated reference to the CASAC Ozone Panel recommendation that the primary standard be set within a specific narrow numerical range, i.e., 0.060 – 0.070 ppm. In my opinion, the CASAC Ozone Panel moved from the Science arena into the Policy arena in advocating an upper bright line value of

0.070 ppm for the primary standard. That value represents the personal judgment of the Ozone Panel Members, not just their interpretation of the Science.

The EPA Administrator, under the authority of the Clean Air Act, has the exclusive responsibility and authority for making policy judgments, informed by science, in setting the ozone standard. Supreme Court Justice Stephen Breyer, in the landmark case, *Whitman versus American Trucking Association* (531 U.S. 457, 2001), offered “common sense” guidance for setting the standards for criteria pollutants such as ozone. He noted that while the Administrator cannot consider cost in setting air quality standards for the criteria pollutants, the EPA Administrator need not set standards at zero risk. He advised the Administrator to use judgment in a “comparative health” context when “deciding what risks are acceptable in the world in which we live.”

In short, Justice Breyer recognized that every day life carries with it a variety of risks. Justice Breyer’s opinion provides “common sense” guidance for deciding how low is low enough in setting air quality standards – the acceptable risk level and associated numerical level of the standard are policy judgments that should be informed by science. In my opinion, the Administrator could have made a policy judgment, informed by science, with selection of a numerical value for the ozone primary standard as high as the 1997 primary standard of 0.08 ppm. His selection of a lower value was consistent with the original advice of his own staff – 0.075 ppm up to a level slightly below the current standard. The CASAC Ozone Panel, in proposing a bright line upper limit of 0.070 ppm, offered their collective judgment on – “what risks are acceptable in the world in which we live.” That is their policy choice, it should not be postured as being exclusively science based. Science alone can never provide a basis for deciding how low is low enough, policy judgments are always required in deciding “what risks are acceptable.” Any specific numerical value for the Standard has an associated “acceptable risk value,” even if the level of acceptable risk has not been explicitly stated.

The CASAC Ozone Panel’s draft letter dated March 26, 2008 continues to suggest that somehow science and scientists alone can establish the appropriate level of the NAAQS for ozone. If the CASAC Ozone Panel decides to submit a letter to the Administrator on the Final Ozone Rule, I suggest they clarify the distinction between science and judgment in offering their opinion on the level of the ozone standard. I urge the CASAC Ozone Panel to acknowledge that the numerical level they have advocated reflects their personal policy preferences. Likewise, in arguing for “further lowering the national ambient ozone standards,” I urge the CASAC Ozone Panel to acknowledge that this is a collective wish that goes well beyond considering just the available scientific information. How low is low enough for the ozone standard is ultimately a policy judgment informed by scientific information and analysis.

References

1. McClellan, R. O. Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.
2. Brauer, M., Frampton, M.W., Koutrakis, P., McClellan, R.O., McDonnell, W.F., Moolgavkar, S., North, D. W., Smith, A.E., Smith, R.L., Utell, M.J. Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone. Comments on Na-

tional Ambient Air Quality Standards for Ozone: Proposed Rule, Federal Register, Vol. 72, No. 132/Wednesday, July 11, 2007, pp 37818-37919, Docket ID No. EPA-HQ-OAR-2005-0172, submitted October 9, 2007.