

**U.S. Environmental Protection Agency
Office of Research and Development**

BOARD OF SCIENTIFIC COUNSELORS

**Conference Call Summary
July 29, 2005
1:00 p.m. – 3:00 p.m. EDT**

Welcome and Overview

Dr. James Johnson (Howard University), Chair of the Board of Scientific Counselors (BOSC), welcomed the Executive Committee members and explained that the purpose of the conference call was to review the draft *Particulate Matter and Ozone Research Program Review Report*. He presented the timeline for the report: the project started in March 2005, and the final draft was completed April 12, 2005. A review of the report at the June 2005 Executive Committee meeting resulted in several substantive revisions. It was decided, therefore, that the BOSC Executive Committee would hold this conference call to review the changes before approving the final draft.

Dr. Johnson thanked Dr. Rogene Henderson (Lovelace Respiratory Research Institute), who served as the Chair, and Dr. Juarine Stewart (Morgan State University), who served as the Vice-Chair, of the Particulate Matter and Ozone Research Subcommittee, and the other members of the Subcommittee for their efforts on the draft report. He mentioned that this meeting will include remarks by Ms. Lorelei Kowalski (EPA/ORD), Designated Federal Officer (DFO) for the BOSC Executive Committee, followed by Dr. Henderson's overview and discussion of the revisions to the draft report. Dr. John Giesy (Michigan State University) and Dr. Johnson will lead further discussions, and Dr. Johnson will ask for the Executive Committee's approval of the report. Time also will be allotted for public comment.

DFO Remarks

Ms. Kowalski reiterated that this meeting was convened specifically to discuss the Particulate Matter and Ozone Research Subcommittee's revised draft program review report. To ensure there was a quorum of BOSC Executive Committee members present, Ms. Kowalski asked the participants on the conference call to identify themselves. A list of the participants is attached to this summary.

Ms. Kowalski stated that the BOSC is a Federal Advisory Committee and subject to the rules of the Federal Advisory Committee Act (FACA). Therefore, this conference call was open to the public, and time was designated for public comment. The meeting minutes will be available to the public on the BOSC Web Site after certification by the BOSC Chair, Dr. Johnson. Notice of this conference call was published in the *Federal Register*. Ms. Kowalski established an electronic public docket for the meeting, which can be accessed at www.epa.gov/edocket. The

number to search for this docket is ORD/2005/0020. Ms. Kowalski added that all appropriate ethics requirements were satisfied for this call. She asked the members to notify her if they have any potential conflicts of interest.

The purpose for this call was to come to agreement on the revisions to the draft program review report. Dr. Henderson will finalize the report based on the comments discussed today. Ms. Kowalski asked the members to submit their homework timesheets to her as soon as possible.

Overview and Revisions to the Report

Dr. Henderson reviewed the revisions that had been made to the draft *Particulate Matter and Ozone Research Program Review Report*. She thanked everyone for their comments and stated that the report was much improved as a result of their input. She explained that one change, inadvertently, had not been made. On page 8, after the Executive Summary, at the beginning of the charge questions, the intent was to change the wording of the long-term goals (LTGs) back to the original wording. She stated that the original wording had not been inserted yet, so the current draft contains the proposed revised text. Dr. Henderson sent out an e-mail earlier in the day containing the original wording.

The second revision was in response to a comment that there should be a conclusion about the Subcommittee's opinion of the program's communication. Dr. Stewart wrote and added Conclusion 10 on page 5 to address that concern. Dr. Henderson added that Dr. Giesy had contributed several comments. His first comment concerned the section about the Office of Management and Budget's (OMB) Program Assessment Rating Tool (PART). The report does not provide direct advice on how a scientific research program could improve the way it is reviewed by the PART process. He also had asked about EPA's role in the health benefits research area and how it fits with the National Institutes of Health (NIH). To address Dr. Giesy's concerns, Conclusion 1 and Recommendation 1 were revised. The revised text for Conclusion 1 now reads: "The Subcommittee finds that the PART process for evaluating the useful outcomes of the activities of governmental agencies is difficult to apply in evaluating scientific research. The purpose of the EPA research effort is to reduce the uncertainties associated with setting regulations to protect public health and the environment. This type of focused, applied research is not usually funded by the National Institutes of Health, and proprietary research conducted by industry is not available for public use. The metric of success for the ORD research effort is the extent to which the outputs of the research are used by the regulatory offices to set appropriate regulations for the protection of public health and the environment (outcome)."

The revised wording for Recommendation 1 now reads: "The Subcommittee recommends that ORD maintain a periodic, formalized process for assessing its primary stakeholders' perception of and satisfaction with its role in the source-to-health outcome process. Such an assessment should provide information needed for the PART review. As stated in the conclusions, the metric of success for the program is the extent to which the outputs of the research are used by the regulatory offices to set appropriate regulations for protection of public health and the environment."

Dr. Henderson asked Dr. Giesy if those changes addressed his concerns. Dr. Giesy replied that he was very pleased; all of his points were addressed, and it was written very eloquently. Dr. Henderson commented that she was glad he was pleased because he had some very thoughtful comments, which were exactly what was needed, i.e., help in how to handle the PART process.

The next revision was in response to several comments suggesting that some of the recommendations were either oblique or not appropriate for the program under review. To address this concern, former Recommendations 2 and 4 were combined into a new Recommendation 3. Dr. Henderson explained that the Subcommittee tried to be more specific about how to implement the recommendations. The new Recommendation 3 states: “The Subcommittee recommends structuring the performance for the second long-term goal around two to three hypothesis-driven pilot studies that would demonstrate the source-to-health outcome and should provide a reasonable metric to measure the success of the program, both from a science and a policy perspective.” She added that they recommended an expert panel or workshop to review these pilot studies and follow their progress. The expert panel could help define a baseline for the major current uncertainties. From that baseline, the panel can measure towards eliminating those uncertainties.

The next revision emphasized the Subcommittee’s support of the current balance between extramural and intramural research. Recommendation 6 was expanded to state that the balance should be maintained, even in the event of reduced funding.

Former Recommendations 8 and 9 were deleted. Recommendation 8 had suggested that the group develop a methodology to clarify how the cost effectiveness of its regulations could be quantified. Dr. Henderson explained that this is social science and outside the realm of the program’s expertise. Former Recommendation 9 was not very clear and was based on one member’s interest in infectious diseases.

The current Recommendation 8 was modified to state that the multi-year plan (MYP) should “... include a discussion indicating how the goals set out by the NRC flow into the crosscutting research issues and how these are embodied under the two long-term goals. If this discussion is in the Research Strategy for the program, the MYP needs to be organized to make obvious the connection between the research and the NRC goals.”

Former Recommendation 5, which included two ideas, was divided into the current Recommendations 4 and 7. Recommendation 4 was revised to read, “Recognizing that EPA faces serious research resource constraints, the Subcommittee nevertheless recommends that ORD reconsider the decision to completely disinvest in ozone research. Continuing research is required for effective ozone standard setting to protect public health and for improved air quality management in regard to sources of ground-level ozone.” Recommendation 7 states that funding decisions for any active intramural projects should undergo review by the Air Research Coordination Team. It had been mentioned in the BOSC review that the conclusions and recommendations for the ozone program should be moved up on the list. As a result, those items, both the conclusion and the recommendation, were moved up to number 4 on both lists.

Dr. Henderson indicated that several editorial changes had been made in response to suggestions. To avoid confusion, the report refers to “NRC suggestions” instead of “10 or 12 NRC recommendations.” Dr. George Lambert (University of Medicine and Dentistry of New Jersey) had recommended including text about the program’s annual savings (approximately \$100 billion attributed to air pollution controls) in the conclusion. Dr. Henderson explained that this suggestion was not included because, although EPA had provided the data, the Subcommittee had not made this conclusion, nor had the information been verified. This statement was left, however, in the introductory material.

Discussion

Dr. Johnson asked Dr. Giesy to discuss any further considerations to the draft report. Dr. Giesy stated that he had crosschecked the revised report with the meeting minutes and found that all comments had been incorporated. He added that the report was in good shape. Dr. Johnson mentioned that he had searched the report to ensure that the word “fine” had been changed to “fine/ultrafine” where appropriate. He noted that the report also is clear now regarding the 10 NRC goals that were expanded to make a total of 12 goals.

Dr. George Daston (Proctor & Gamble) commented that he agreed with the wording in Recommendation 4 about ozone research continuing past 2012, but he found it difficult to locate the research that was anticipated to be valuable. He identified two items that, if the research were curtailed, would cause concern: (1) continuing uncertainty around health effects and the association with increased mortality (bottom of page 19), and (2) uncertainties around unresolved issues regarding sources of ground-level ozone (top of page 20). He recommended including those items in Recommendation 4 in the Executive Summary. This would clarify what purpose-driven ozone research needs to be done. Dr. Henderson agreed to add these items (i.e., health effects and monitoring).

Dr. Giesy noted that all abbreviations in the document had been defined, and the footnotes and citations were accurate. He suggested changing the wording in Part A of Recommendation 2 to read “by 2012” instead of “in 2012.” Dr. Henderson agreed with this change.

Public Comment

Douglas Austin, from the Ozone Transport Commission, was invited to comment. He stated that he was there only to listen, but that he would look at the recommendations and pass them along to the Ozone Transport Commission Director for his information. He did not wish to comment.

Discussion (continued)

Dr. Lambert suggested that the PART process should not be the first item in Conclusion 1. He also recommended emphasizing that the program has averted a significant number of premature deaths and saved approximately \$100 billion. These are important results of the program, and the data are documented with references from the White House. Congress and the public also read these documents; therefore, he suggested including these results as outcomes.

Dr. Johnson agreed with the importance of the program's results, but cautioned that they would be considered outcomes from the regulatory offices, not the Particulate Matter and Ozone Research Program, which is under review. The text states that "the metric for success for this program is the extent to which the outputs of the research are used by the regulatory offices to set appropriate regulations." Dr. Johnson also noted that these results were included in the Executive Summary. It was decided that the document would not be changed to emphasize this point.

Referring to Dr. Lambert's first suggestion, Dr. Johnson recommended making the PART discussion Conclusion 3 instead of Conclusion 1. The revised text would have Conclusion 1 begin with "The Subcommittee finds that PM & O₃..." Conclusion 2 would begin with "The Subcommittee finds that the outputs produced..." The third conclusion discusses the relationship of the outputs to the outcomes. Both Drs. Henderson and Johnson agreed that this was a good recommendation.

Approval of the Report

Dr. Johnson reviewed the recommended revisions: (1) rearrange the conclusions so that the first conclusion becomes the third one; (2) on page 8, use the original wording for the LTGs as they are stated in the MYP that has been reviewed; (3) revise Recommendation 4 to include monitoring and health; and (4) change the wording in Recommendation 2 from "in 2012" to "by 2012." Dr. Giesy added a fifth revision: change "principle investigator" to "principal investigator."

Dr. Johnson stated that these changes were in addition to the changes that were reviewed earlier. He asked for a recommendation from the BOSC for approval of the report as amended. It was moved and seconded that the BOSC accept the report as amended. Dr. Johnson stated for the record that the report was adopted unanimously by the BOSC Executive Committee members who were present.

Dr. Johnson thanked Mr. Austin for joining the discussion.

Dr. James Clark (Exxon Mobil Research & Engineering Co.) commented that the review of the Human Health Research Program involved a similar struggle with outputs and outcomes and the way ORD influences public health. He noted that the wording in Conclusion 1 about the metric for success for ORD research fits many upcoming PART and program reviews.

Dr. Johnson responded that, at the next meeting, the BOSC Executive Committee will discuss the lessons learned in conducting the program reviews and preparing the reports. He asked Dr. Henderson to highlight the approach that the Subcommittee took in defining outcomes versus outputs, including outcomes for other agencies or other parts of EPA. He added that this would be beneficial for everyone to see.

Dr. Henderson asked if Ms. Kowalski's staff could work with her to revise the report, adding that she would like to finish it as soon as possible. Ms. Kowalski replied that she would assist in

finalizing the report. She added that the contractor was taking notes so that the exact wording changes could be made.

Dr. Johnson adjourned the meeting at 2:00 p.m.

Action Items

- ✧ Dr. Henderson will revise Recommendation 4 to include health effects and monitoring.
- ✧ Dr. Henderson will finalize the report based on the comments received during this call.
- ✧ Ms. Kowalski will assist Dr. Henderson in finalizing the report.
- ✧ Dr. Henderson will highlight the approach that the Subcommittee took in defining outcomes versus outputs.
- ✧ Executive Committee members will submit their homework timesheets to Ms. Kowalski as soon as possible.

BOSC Executive Committee Members

James H. Johnson, Jr., Ph.D.
Chair, BOSC Executive Committee
Dean, College of Engineering, Architecture,
and Computer Sciences
Howard University
2366 Sixth Street, NW, Room 100
Washington, DC 20059
Phone: 202-806-6565
Fax: 202-462-1810
E-mail: jj@scs.howard.edu

James R. Clark, Ph.D.
Exxon Mobil Research & Engineering Co.
3225 Gallows Road, Room 3A412
Fairfax, VA 22037
Phone: 703-846-3565
Fax: 703-846-6001
E-mail: jim.r.clark@exxonmobil.com

George P. Daston, Ph.D.
Miami Valley Laboratories
The Proctor & Gamble Company
11810 E. Miami River Road
Cincinnati, OH 45252
Phone: 513-627-2886
Fax: 513-627-0323
E-mail: daston.gp@pg.com

Clifford S. Duke, Ph.D.
Director of Science Programs
The Ecological Society of America
1707 H Street NW, Suite 400
Washington, DC 20006
Phone: 202-833-8773, ext. 202
Fax: 202-833-8775
E-mail: csduke@esa.org

John P. Giesy, Ph.D.
Distinguished Professor of Zoology
Professor of Veterinary Medicine
Department of Zoology
Natural Science Building
Michigan State University
East Lansing, MI 48824-1222
Phone: 517-353-2000
Fax: 517-432-1984
E-mail: jgiesy@aol.com

Rogene F. Henderson, Ph.D., DABT
Chair, Particulate Matter/Ozone
Subcommittee
Scientist Emeritus
Lovelace Respiratory Research Institute
2425 Ridgcrest Drive, S.E.
Albuquerque, NM 87108
Phone: 505-348-9464
Fax: 505-348-4983
E-mail: rhenders@lrri.org

Juarine Stewart, Ph.D.
Vice-Chair, Particulate Matter/Ozone
Subcommittee
Dean
School of Computer, Mathematical, and
Natural Sciences
Morgan State University
1700 E. Cold Spring Lane
Baltimore, MD 21251
Phone: 443-885-4515
Fax: 443-885-8215
E-mail: jstewar2@jewel.morgan.edu

SAB Liaison to BOSC:

George Lambert, M.D.

Director

The Center for Childhood Neurotoxicology
and Exposure Assessment

Robert Wood Johnson Medical School

University of Medicine and Dentistry

of New Jersey

170 Frelinghuysen Road

Piscataway, NJ 08854

Phone: 800-644-0088

Fax: 732-253-3520

E-mail: glambert@umdnj.edu

Other Attendees:

Douglas Austin

Ozone Transport Commission

Contractor Support:

Amy Lance

The Scientific Consulting Group, Inc.

656 Quince Orchard Road, Suite 210

Gaithersburg, MD 20878

Phone: 301-670-4990

Fax: 301-670-3815

E-mail: alance@scgcorp.com

Committee Staff:

Lorelei Kowalski

Designated Federal Officer

U.S. Environmental Protection Agency

Office of Research and Development

Mail Code 8104R

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Phone: 202-564-3408

Fax: 202-565-2911

E-mail: kowalski.lorelei@epa.gov

**BOARD OF SCIENTIFIC COUNSELORS
EXECUTIVE COMMITTEE MEETING
AGENDA**

**Friday, July 29, 2005
1:00 p.m. – 3:00 pm Eastern**

**CONFERENCE CALL
Participation by Teleconference Only**

1:00-1:10 p.m.	Welcome and Overview - Purpose of Teleconference Call	Dr. James H. Johnson, Jr. Chair, BOSC Executive Committee
1:10 – 1:15p.m.	DFO Remarks	Lori Kowalski, Office of Research and Development
1:15-1:35 p.m.	Particulate Matter(PM)/Ozone Subcommittee Draft Report - Overview - Revised responses to charge questions	Dr. Rogene Henderson, Chair PM/Ozone Subcommittee
1:35-1:50 p.m.	Discussion	Dr. John Giesy, BOSC Executive Committee/ Dr. James Johnson, Jr., Chair BOSC Executive Committee
1:50-2:00 p.m.	Public Comment	
2:00 – 2:45 p.m.	Discussion (Continued)	Dr. John Giesy, BOSC Executive Committee/ Dr. James Johnson, Jr., Chair BOSC Executive Committee
2:45 – 3:00 p.m.	Final Report - Identification of Additional Changes - Approval by Executive Committee	Dr. James H. Johnson, Jr. Chair, BOSC Executive Committee
3:00 p.m.	Adjourn	