

HUMAN HEALTH MID-CYCLE REVIEW SUBCOMMITTEE

Conference Call Summary
Thursday, March 15, 2007
12:30 p.m. – 1:30 p.m. Eastern Time

Welcome

Dr. Jim Clark, Exxon-Mobil Corporation, Subcommittee Chair

Dr. Jim Clark, Subcommittee Chair, welcomed the Human Health Mid-Cycle Review Subcommittee members to the conference call and thanked them for participating in this review. He asked Virginia Houk, the Designated Federal Officer (DFO) for the Subcommittee to address some administrative issues.

Administrative Procedures

Virginia Houk, EPA/Office of Research and Development, Designated Federal Officer

Ms. Virginia Houk thanked the Subcommittee members for their efforts in conducting this mid-cycle review. She then reviewed the Federal Advisory Committee Act (FACA) procedures that are required for all Board of Scientific Counselors (BOSC) Subcommittee meetings. As the Designated Federal Officer (DFO) for the Human Health Mid-Cycle Review Subcommittee, Ms. Houk serves as the liaison between the Subcommittee and ORD. She explained that the BOSC is a Federal Advisory Committee that provides independent peer review for EPA's Office of Research and Development (ORD). The purpose of the mid-cycle review is to gauge the progress that has been made and the changes that have been implemented since the BOSC reviewed the program 2 years ago, and to obtain advice on future directions for the program. For this mid-cycle review, the Subcommittee was provided a list of charge questions by the BOSC Executive Committee; these questions were designed to obtain feedback from the program staff on both management and scientific issues.

This is the third meeting for the Human Health Mid-Cycle Review Subcommittee. A conference call was held on January 9, followed by a face-to-face review meeting on January 24, 2007, which was held in Arlington, Virginia. The Subcommittee is in the process of developing a draft report that will be submitted to the BOSC Executive Committee for review. The Executive Committee will revise the report as it deems appropriate and submit it to ORD. The rights of decision making on how to respond to the review reside with EPA, and program implementation is the responsibility of the Agency.

Ms. Houk stated that it is her responsibility as the DFO to ensure that the Subcommittee's conference calls and meetings comply with all FACA rules. All meetings and conference calls involving substantive issues, whether in person, by phone, or by e-mail, that include one-half or

more of the Subcommittee members must be open to the public and a notice must be placed in the *Federal Register* at least 15 days prior to the call or meeting. Issues that are preparatory or administrative in nature are exempt from this requirement. The Subcommittee Chair and DFO must be present at all conference calls and meetings. The information for this conference call was entered into the federal docket management system (<http://www.regulation.gov>, Docket ID EPA-HQ-ORD-2006-0978).

During this conference call, items will be discussed according to the agenda, and a summary of the call will be made available to the public after certification by the Chair of the Subcommittee. The Chair must certify the summary within 90 days of the call or meeting. The summary then will be posted on the BOSC Web Site (<http://www.epa.gov/osp/bosc>). All advisory committee documents also are available to the public.

Ms. Houk has worked with EPA officials to ensure that all appropriate ethics regulations have been satisfied; each Subcommittee member has filed a confidential disclosure form and completed the required ethics training. Because notes were being taken, Ms. Houk asked speakers to identify themselves when making a comment. She reported that no requests for public comment were submitted prior to the call, but the agenda allows time for public comment from 1:25 to 1:30 p.m. She will call for public comments at that time and each comment should be limited to 3 minutes.

Discussion of Draft 1 of the Mid-Cycle Report

Human Health Mid-Cycle Review Subcommittee

Dr. Clark asked that each member consider whether consensus has been reached as the draft response to each charge question is discussed. Editorial and other comments should be sent to Dr. Clark and Ms. Houk. Dr. Clark will consolidate the comments and prepare a second draft of the report for review by the Subcommittee. Dr. Clark said that he will work on the tone of the report so that it does not read like this was a closed meeting with EPA. In the next draft, he will make it clear that this was a FACA review.

Charge Question #1

Dr. Clark stated that Dr. Joe Landolph had the lead for this question and he did a good job in drafting the response. In an effort to shorten the main body of the report, Dr. Clark moved some of the text to an appendix. He did not want to delete the material because it captured the programmatic changes instituted by EPA in response to the BOSC program review. Dr. Elaine Symanski thought this was a good approach. Dr. Landolph indicated that there may be a few sentences that he would like reinserted into the main body of the report. There were several points (on pages 4, 5, and 6) that he would like to reinsert. He agreed to pull out the text and send it to Dr. Clark. He will eliminate the track changes edits and send Dr. Clark a clean version of the text. In response to Dr. Landolph's inquiry, Dr. Clark said that he removed the reference to the rating on page 13 because the rating will be addressed only in charge question #5. Dr. Clark asked if there was consensus on the response to this charge question, stating the he tried to incorporate all of Dr. Tim Buckley's comments. Dr. Buckley said he liked the way the question was addressed and he was comfortable with the response. He had one additional comment to add to the response. He would have liked to see EPA address each of the issues raised in the program review in the revised Multi-Year Plan (MYP). He did not think ORD's response was

meaningful until it was translated into the program through the MYP. Dr. Buckley will send a sentence that captures this comment to Dr. Clark and Ms. Houk for inclusion in the revised report. Dr. Clark asked if Drs. Symanski and Landolph were comfortable with this addition. Both indicated that they were. Dr. Clark noted that some of Dr. Buckley's edits of the response to this question were moved to the response to charge question #2. Dr. Clark said that he will incorporate any changes submitted by the members for this question into the revised draft of the report.

Charge Question #2

Dr. Clark said that he used Dr. Buckley's wording about the revised objectives. There was much remaining to be done but it was clear that the program had made some changes. Dr. Clark mentioned that he did not include the comment about tracking difficulty. Dr. Buckley said that he thought the response to this question was fine. Dr. Symanski had no comments and Dr. Landolph indicated that he already sent his comments to Dr. Clark, and he was comfortable with this response. Dr. Buckley noted that in the last paragraph in response to charge question #2, there was discussion about a conceptual framework diagram that was presented at the meeting. The Subcommittee discussed how this could be enhanced and Dr. Buckley wondered if the report should be more specific and capture the comments from the face-to-face meeting. Dr. Clark said that he would look through the meeting summary and try to capture those comments.

Charge Question #3

Dr. Buckley said that he was comfortable with the response to this question. Both Drs. Clark and Landolph provided comments on this response. Dr. Buckley asked if they approved of how their comments were incorporated. Referring to the bottom of page 6, Dr. Clark thought the program should receive credit for their bibliometric analysis—the numbers in that analysis looked good to him. He suggested deleting the word “While” from the sentence “While the HHRP has conducted a comprehensive bibliographic analysis of publications and their impact, the MYP includes no consideration of how such metrics could be applied.” The word “but” should be inserted after “impact,” so that the revised sentence would read “The HHRP has conducted a comprehensive bibliographic analysis of publications and their impact, but the MYP includes no consideration of how such metrics could be applied.” Dr. Landolph agreed that the program should get credit for its productivity and good bibliometric analysis. Dr. Buckley agreed but said he would like to see the program take the analysis a bit further. Dr. Clark asked for some examples of how to take the analysis further. Should a certain number of the papers be “hot papers”? What guidance can we give them? Dr. Buckley mentioned the separation of intramural and extramural publications in the analysis and to look at trends over time. He was not certain how specific the Subcommittee should be on this point. Dr. Landolph suggested providing some examples to guide them. He was very favorably impressed with the bibliometrics; the program is publishing in high impact journals, there are a number of hot papers, and the publications are highly cited. Dr. Clark asked if Dr. Buckley wants the program to compare its bibliometrics with other federal programs or with other EPA programs. He asked Dr. Buckley to provide some examples without mandating certain actions. Dr. Symanski commented that publications should be linked to a performance measure so that they serve some purpose as a metric of performance. Dr. Landolph mentioned the arsenic and dioxin successes discussed at the face-to-face meeting and thought they should be mentioned in the report. Dr. Buckley thought that comment should be placed in the context of the charge questions. Dr. Symanski pointed out that the mid-cycle

review was not intended to be a rigorous review of the program's science. Therefore, she did not think such a comment was appropriate. Dr. Clark agreed that this was not intended to be as in depth as a program review and he was concerned about going beyond the scope of the charge.

Charge Question #4

Dr. Symanski said that she incorporated the comments she received on this response, noting that she had difficulty with some of Dr. Landolph's comments. Some of them did not appear to be relevant to this question. Dr. Landolph responded that he would defer to Dr. Symanski's expertise on this response. Dr. Buckley thought this was a strong response. Dr. Clark reiterated that he removed any reference to ratings from the individual charge question responses, noting that the rating will be addressed in charge question #5.

Charge Question #5

Dr. Clark explained that the Subcommittee is using the new rating tool approved by the BOSC Executive Committee in response to this question. The consensus rating was "exceeds expectations." It appears that the program is moving in the right direction; the progress that has been made has been satisfactory but when the proposed changes are considered, the program exceeds expectations. Dr. Landolph said he was happy with the response to this question. Dr. Buckley liked the way the response was crafted. In the first paragraph, he proposed adding a sentence after the words ". . . then are discussed with HHRP scientists." The sentence should say something like: ORD should take a leadership role here, providing a strong rationale for selecting chemicals for study rather than just responding to what the program office thinks it needs. The MYP should portray ORD's leadership rather than follow the guidance of the program offices. That was a concern that Dr. Buckley had about the MYP. Dr. Clark asked Dr. Buckley to draft a sentence that could be inserted in this section and send it to him and Ms. Houk. Dr. Buckley agreed to provide the requested sentence. Dr. Clark cautioned him to be careful about the wording because it is important to have both the scientific rationale and the program office rationale. ORD should take the leadership role in explaining why the Agency needs to test certain chemicals and this information should be used to set priorities. Dr. Symanski said that she did not have any comments on this response and that she agreed with it as written.

Executive Summary

Dr. Clark said that he will prepare an Executive Summary (1-2 pages) based on the report. It will include the major conclusions and recommendations of the review. It also will include a brief history and purpose of the review. Dr. Clark asked if the other members were comfortable with him drafting the Executive Summary for their review. All of the members indicated their approval.

Next Steps

Dr. Clark asked how the Subcommittee members would like to proceed in reviewing the Executive Summary and the revised report. It was decided that the Subcommittee members would send their revisions to the report to Dr. Clark and Ms. Houk as soon as possible. Dr. Clark would revise the report and prepare the Executive Summary. He will send the revised

report with the Executive Summary to Ms. Houk for distribution to the Subcommittee members. The Subcommittee members will review the report and Executive Summary and:

- ✧ If they have comments, they will provide them in writing (by e-mail) to Dr. Clark and Ms. Houk and indicate that with these changes they approve the report and Executive Summary, OR
- ✧ If they have no changes, they will send an e-mail to Dr. Clark and Ms. Houk indicating that they approve the report and Executive Summary.

Dr. Clark then will incorporate any final comments into the report so that it can be presented to the BOSC Executive Committee for review at the May 2007 meeting.

Dr. Clark asked Dr. Tilson if there was anything that should be added to the report. Ms. Kowalski, DFO for the BOSC Executive Committee, commented that Dr. Tilson could not respond to that question. He can only correct technical inaccuracies in the report; he cannot comment on what is included, what should be added, or what he thinks of the report.

Dr. Landolph asked Ms. Houk if the members should send her their homework forms. She replied in the affirmative and he asked that she send him another form. Ms. Houk said that she would e-mail the form to the Subcommittee members.

Public Comments

Ms. Houk asked if anyone on the telephone would like to make a public comment. No comments were offered.

Closing Remarks

Dr. Symanski asked if Dr. Clark wanted the members to accept the changes in the file so that the copy they send him will be clean. Dr. Clark replied that all members should accept the changes and send clean files to him and Ms. Houk with their additional comments. Dr. Clark thanked everyone for their comments and adjourned the call at 1:15 p.m.

Action Items

- ✧ Dr. Landolph will provide a clean version of the text that he would like reinserted on pages 4, 5, and 6 of the report in the response to charge question #1 to Dr. Clark and Ms. Houk.
- ✧ Dr. Buckley will send a sentence to Dr. Clark and Ms. Houk about how he would have preferred to see EPA address each of the issues raised in the program review in the revised Multi-Year Plan (MYP).
- ✧ Dr. Clark will look through the summary of the face-to-face meeting for Dr. Buckley's comments about the conceptual framework diagram that was presented at that meeting. He will include the Subcommittee's comments on how this could be enhanced in the response to charge question #2.

- ✧ Dr. Buckley will draft a sentence to be inserted in the first paragraph after the words “then are discussed with HHRP scientists” in the response to charge question #5. The sentence will capture the idea that ORD should take a leadership role here, providing a strong rationale for selecting chemicals for study rather than just responding to what the program office thinks it needs. The MYP should portray ORD’s leadership rather than follow the guidance of the program offices.
- ✧ The Subcommittee members will provide their specific comments/rewrites for each of the charge questions to Dr. Clark and Ms. Houk.
- ✧ Dr. Clark will revise the draft report based on the comments/rewrites provided by the Subcommittee members.
- ✧ Dr. Clark will draft an Executive Summary for the report.
- ✧ Dr. Clark will send the revised report and Executive Summary to Ms. Houk for distribution to the Subcommittee.
- ✧ Subcommittee members will review the revised report and Executive Summary and send final comments and/or a statement of their approval of the report to Dr. Clark and Ms. Houk.
- ✧ Ms. Houk will e-mail homework forms to the Subcommittee members.
- ✧ Subcommittee members will complete their homework forms and send them to Ms. Houk.

PARTICIPANTS LIST

Subcommittee Members

James R. Clark, Ph.D., Chair

Exxon Mobil Research and Engineering
Company
Environmental, Safety, Civil & Marine Division

Timothy Buckley, Ph.D., CIH

Associate Professor
Chair, Division of Environmental Health
Sciences
Ohio State University School of Public Health

Joseph Landolph, Ph.D.

Associate Professor of Molecular Microbiology,
Immunology and Pathology
University of Southern California
Keck School of Medicine

Elaine Symanski, Ph.D.

Associate Professor
University of Texas Health Science Center
School of Public Health

Designated Federal Officer

Virginia Houk

U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects
Research Laboratory

EPA Participants

Alva Daniels

U.S. Environmental Protection Agency
Office of Research and Development
National Risk Management Research Laboratory

Andrew Geller, Ph.D.

U.S. Environmental Protection Agency
Office of Research and Development
National Health and Environmental Effects
Research Laboratory

Ross Highsmith, Ph.D.

U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory

Lorelei Kowalski

U.S. Environmental Protection Agency
Office of Research and Development
Office of Science Policy

Hugh Tilson, Ph.D.

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

Contractor Support

Beverly Campbell

The Scientific Consulting Group, Inc.



APPENDIX A: Teleconference Agenda

HUMAN HEALTH MID-CYCLE TELECONFERENCE MEETING AGENDA

**March 15, 2007
12:30 p.m. – 1:30 p.m.**

Thursday, March 15, 2007

12:30-12:35 p.m.	Welcome	Dr. Jim Clark Chair, HH Mid-Cycle Subcommittee
12:35-12:40 p.m.	Administrative Procedures - FACA Rules	Virginia Houk (EPA) DFO, HH Mid-Cycle Subcommittee
12:40-1:25 p.m.	Discussion of Draft 1 of Mid-Cycle Report - Charge Question #1 - Charge Question #2 - Charge Question #3 - Charge Question #4 - Charge Question #5 - Executive Summary	HH Mid-Cycle Subcommittee Dr. Joseph Landolph Dr. Jim Clark Dr. Timothy Buckley Dr. Elaine Symanski Dr. Jim Clark Dr. Jim Clark
1:25-1:30 p.m.	Public Comments	
1:30 p.m.	Adjourn	