

**HUMAN HEALTH RISK ASSESSMENT (HHRA) SUBCOMMITTEE**

**Conference Call Summary**  
**Monday, January 28, 2008**  
**3:30 p.m. – 5:30 p.m. Eastern Time**

**Welcome**

*Dr. George Daston, Procter & Gamble, HHRA Subcommittee Chair*

Dr. George Daston, Chair of the HHRA Subcommittee, welcomed participants to the Board of Scientific Counselors (BOSC) HHRA Subcommittee conference call. The purpose of this call is to discuss the summary of the report that the Subcommittee members prepared as part of their review of the National Center for Environmental Assessment's (NCEA) HHRA Program. Dr. Daston requested that the Subcommittee members discuss substantive and/or technical changes to the summary. Minor grammatical errors will not be the focus of this call; Subcommittee members should transmit any grammatical corrections to Dr. Daston and Ms. Joanna Foellmer, Designated Federal Officer (DFO) for the Subcommittee, after the teleconference.

**Administrative Procedures**

*Ms. Joanna Foellmer, U.S. Environmental Protection Agency (EPA), NCEA, DFO*

Ms. Foellmer thanked the Subcommittee members for their participation. The BOSC HHRA Subcommittee is a federal advisory committee that has been asked to respond to a set of charge questions as part of its review of NCEA's HHRA Program. As DFO, Ms. Foellmer serves as the liaison between the Subcommittee members and the Agency and is responsible for ensuring that the Subcommittee members comply with the Federal Advisory Committee Act (FACA). Ms. Foellmer briefly explained the FACA requirements. All meetings involving substantive issues—whether in person, by phone, or by e-mail—are open to the public. This applies to all group communications that include at least one-half of the Subcommittee members. All meetings must be announced in the *Federal Register* at least 15 calendar days in advance of the meeting. The *Federal Register* notice for this meeting was published on January 11, 2008. An electronic public docket for the call was established on the Federal Docket Management System (FDMS), which can be accessed at <http://www.regulations.gov>. The Docket Identification Number is EPA-HQ-ORD-2007-0920. In addition, all advisory committee documents are available to the public. The Subcommittee Chair and DFO must attend all meetings. There is time set aside for public comment during each meeting. No advance requests for comment have been submitted by the public, but time has been set aside for public comment at 4:10 p.m. Any comments must be limited to 3 minutes each.

This is the fifth public meeting of the HHRA Subcommittee. The Subcommittee members convened for public calls on October 2, 2007, October 31, 2007, and December 20, 2007, and for a face-to-face meeting in Bethesda, Maryland, on November 14–16, 2007.

A contractor is recording the call and will prepare a summary of the discussions. Ms. Foellmer reminded all participants to identify themselves when speaking and to speak clearly. She asked that participants mute their phone lines when they are not speaking to minimize background noise.

**Draft Report Discussion**

*Dr. George Daston, HHRA Subcommittee Chair*

Dr. Daston apologized for the short turnaround time allotted to the Subcommittee members for reviewing the summary. He explained that he had prepared the summary by incorporating verbatim sentences that the Subcommittee members had composed regarding the summary assessments. In addition, he paraphrased other significant points made throughout the report. The summary reflects the organization of the Subcommittee's charge.

Mr. Bruce Allen said that the summary was well written, and he had few comments. He suggested deleting the third paragraph on page 2 because it was repetitive with the preceding paragraph and it incorrectly referenced items in Appendices A and B. Dr. Daston agreed.

Mr. Allen directed the Subcommittee members to the last sentence of the summary, which describes Long-Term Goal (LTG) 3. It reads, "The rating of Meets Expectations therefore should consider the above mentioned factors." He pointed out that summary statements were not repeated at the end of the discussions for the other LTGs, and he suggested removing this sentence. Dr. Daston agreed. Dr. Richard Corley remarked that he thought summary statements were listed for the other LTGs. Mr. Allen explained that a summary statement was given at the beginning of each paragraph describing an LTG, but it was not necessary to repeat the statement at the end of the paragraph.

Mr. Allen questioned what was meant by the term "stretch goal." Dr. Daston explained that the term is common among Procter & Gamble associates; it is defined as a goal that transcends expectations. Dr. Daston said that he would rephrase this term throughout the summary.

Mr. Allen confirmed that editorial comments could be sent to Dr. Daston and Ms. Foellmer after the teleconference.

Dr. Mark Utell noted that the summary reflected the general opinions of the Subcommittee members. He stated that he was concerned about the balance of the LTG discussions in the summary. Recommendations pertaining to LTG 1 seemed to be disproportionately highlighted in comparison to the recommendations pertaining to LTGs 2 and 3. Dr. Utell noted that the Subcommittee members had concerns regarding LTGs 2 and 3, but these were missing from the summary. Specifically, the HHRA Program is transitioning from the criteria documents to the integrated science assessments (ISAs), and the Subcommittee members had questioned how adequately the ISAs would serve as a replacement. Dr. Daston answered that the discussions related to LTG 3 were sparse because the transition to ISAs is in its early phases, and the Subcommittee members were unable to assess the quality of the product at this point. Dr. Utell agreed that there are few ISAs available to review; nevertheless, he thought that the Subcommittee members' concerns about identifying gaps in the research and integrating old and new studies should be noted in the summary. The ISAs will inform the Agency and the public so the Subcommittee's review of these documents should be balanced with the review of LTG 1.

Dr. Daston clarified that the summary assessment for LTG 3 in the report body reflects Dr. Utell's comments, but perhaps these recommendations also should be listed in the program quality section in the summary. Dr. Lauren Zeise stated that program quality is discussed on page 6; she asked how Dr. Utell would suggest changing it. Dr. Utell pointed out the sentence, "We are confident that it will continue to be of high quality." He emphasized qualifying the sentence to reflect the Subcommittee members' concerns. Dr. Daston suggested changing the sentence to, "Because of the newness of the procedure, the Subcommittee withholds judgment as to whether this will be an improvement or an area of concern." Dr. Utell offered to compose a short section explicitly discussing the potential shortcomings of LTG 3. He will transmit this to Dr. Daston and Ms. Foellmer for incorporation into the program quality section of the summary.

Dr. Zeise suggested that the discussion of LTG 3 acknowledge the process involved in preparing an ISA. Stakeholders and congressional staff provide input to the ISAs, and it is unclear at this point whether the ISAs will be considered as useful as the criteria documents. Dr. Daston suggested inserting the language, "The Subcommittee acknowledges that it has had review by other groups, but we still have some concern and uncertainty about the outcome from a process that has only been tried once before." Dr. Utell emphasized that the criteria documents were voluminous, world-class documents, and the ISAs are a variation that may prove equally as important. The Subcommittee members' concerns must be voiced to ensure that the HHRA Program recognizes potential shortcomings early in the process.

Dr. Utell asked for a definition of the acronym UNEP. Dr. Daston replied that it stood for United Nations Environmental Programme. Mr. Allen pointed out that MOU, or memorandum of understanding, also was not defined. Dr. Daston agreed to define those acronyms in the summary. Dr. Utell suggested that a glossary of acronyms be prepared. Dr. Daston will determine whether preparing a glossary is feasible.

Mr. Allen noted that on page 9, the last sentence in the first paragraph refers to a response to Charge Question 2. He recommended amending the sentence as the reference was incorrect. Mr. Allen specified that the sentence immediately precedes the heading for LTG 1 and refers to information being provided by the program and regional offices. Dr. Daston will remove the phrase "as noted in response to question 2" in this section.

Dr. Zeise directed the Subcommittee members to the program quality section on page 6. In the paragraph that follows the recommendations, one sentence reads, "The extent of peer review for [Integrated Risk Information System] IRIS and ISA assessments exceeds any other examples with which the Subcommittee is familiar." She suggested modifying that statement as there may be other documents with more extensive peer review. Dr. Daston will change the phrase "exceeds any other examples" to "exceeds most other examples."

Dr. Corley pointed out that the relevance section on page 3 references the Annual Performance Goals (APGs) for IRIS. One sentence reads, "The Subcommittee understands the philosophy behind the policy, but believes that given current resources, it may be impractical to update all assessments, but unfortunate to remove any." He recommended changing "unfortunate to remove any" to "inappropriate to remove any." Dr. Henry Anderson said that outdated assessments may be based on incorrect conclusions; these assessments should not be retained in the IRIS database. Dr. Daston will change "unfortunate to remove any" to "inappropriate to remove any unless made irrelevant or incorrect because of data that have become available since the review."

Dr. Anderson added that the Subcommittee members had recommended that assessments be updated rather than removed whenever possible.

Dr. Utell asked if the Subcommittee members would have the opportunity to review the intact, finalized report before it is submitted to the BOSC Executive Committee. Dr. Daston agreed that a final review was important. He will incorporate the corrections discussed at this teleconference and Dr. Utell's section regarding LTG 3 concerns. The report then will be transmitted to the Subcommittee members for final approval. Alternatively, if there are substantive and/or technical comments, the Subcommittee will reconvene for a sixth public meeting.

Dr. Anderson directed the Subcommittee members to page 3 of the summary. He pointed out the sentence, "...given the complexity of IRIS reviews, that it should be considered to be an ambitious goal." He suggested changing the phrase "given the complexity of" to "given currently allocated staff and resources for." He noted that the goal is ambitious primarily because resources are lacking. Dr. Daston said that he would incorporate that change.

Dr. Anderson noted the phrase on page 5, "in the absence of either IRIS or [Provisional Peer-Reviewed Toxicity Values] PPRTVs, a chemical may result in being inappropriately elevated in priority," does not consider the possibility that an absence of data also could inappropriately demote the priority of a chemical. Dr. Daston will change "inappropriately elevated in priority" to "inappropriately prioritized."

Dr. Anderson confirmed that typographical corrections should be transmitted to Dr. Daston and Ms. Foellmer.

### **Public Comment**

Dr. Daston called for public comment at 4:10 p.m. No members of the public offered comments.

### **Draft Report Discussion (Continued)**

*Dr. George Daston, HHRA Subcommittee Chair*

Dr. Daston asked if there were any additional comments on the draft report to confirm that the discussion of the summary was complete.

### **Next Steps**

*Dr. George Daston, HHRA Subcommittee Chair*

Dr. Daston reiterated that he will incorporate the Subcommittee members' corrections into the summary, and Ms. Foellmer will transmit the entire report to the Subcommittee members for their review. The report will include two appendices: (1) the Subcommittee roster; and (2) the Charge Questions. Dr. Daston will determine whether a glossary of acronyms is feasible. If so, the Subcommittee members will receive the glossary to review as a third appendix.

Ms. Foellmer requested that Subcommittee members complete their homework sheets and transmit them to her for compensation.

Dr. Daston thanked the members of the Subcommittee for their contributions and adjourned the call at 4:15 p.m.

## Action Items

- ✍ Dr. Daston will:
  - ? Delete the third paragraph on page 2;
  - ? Delete the last sentence of the summary;
  - ? Rephrase the term “stretch goal” throughout the summary;
  - ? Define UNEP and MOU in the summary;
  - ? Determine the feasibility of preparing a glossary of acronyms as a third appendix to the Subcommittee’s report;
  - ? Delete the phrase “as noted in response to question 2 in this section” from page 9, paragraph 1;
  - ? Replace the phrase “exceeds any other examples” with “exceeds most other examples” in the program quality section, page 6;
  - ? Replace “unfortunate to remove any” with “inappropriate to remove any unless made irrelevant or incorrect because of data that have become available since the review” in the relevance section, page 3;
  - ? Replace the phrase “given the complexity of” with “given currently allocated staff and resources for” on page 3; and
  - ? Replace “inappropriately elevated in priority” with “inappropriately prioritized” on page 5.
- ✍ Dr. Utell will compose a short section discussing the Subcommittee’s concerns about LTG 3.
- ✍ Dr. Daston will incorporate Dr. Utell’s discussion of LTG 3 into the program quality section of the summary.
- ✍ The Subcommittee members will submit any corrections of an editorial or nontechnical nature to Dr. Daston and Ms. Foellmer. Dr. Daston will incorporate corrections into the summary.
- ✍ Ms. Foellmer will transmit the entire report, with the revised summary, to the Subcommittee members.
- ✍ The Subcommittee members will review the final report. If changes of a substantive and/or technical nature are warranted, the Subcommittee will reconvene for a sixth public meeting to finalize the report.

- ✍ The Subcommittee members will complete their homework sheets and submit them to Ms. Foellmer for compensation.

## PARTICIPANTS LIST

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## **HUMAN HEALTH RISK ASSESSMENT (HHRA) SUBCOMMITTEE**

### **AGENDA**

**January 28, 2008**

**3:30 p.m. – 5:30 p.m. Eastern Time**

3:30 – 3:35 p.m.	Welcome - Roll Call - Overview of Agenda - Objectives of Call	Dr. George Daston Subcommittee Chair
3:35 – 3:40 p.m.	Administrative Procedures	Joanna Foellmer Subcommittee DFO
3:40 – 4:10 p.m.	Draft Report Discussion	Dr. George Daston Subcommittee Chair
4:10 – 4:25 p.m.	Public Comment	
4:25 – 5:00 p.m.	Draft Report Discussion Continued	Dr. George Daston Subcommittee Chair
5:00 – 5:30 p.m.	Next Steps - Action Items - BOSC Executive Committee Review	Dr. George Daston Subcommittee Chair
5:30 p.m.	Adjourn	