

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

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

6  
7                   **Welcome**

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

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

17  
18                  **Administrative Procedures**

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

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

37  
38                  This is the fifth public meeting of the HHRA Subcommittee. The Subcommittee members  
39                  convened for public calls on October 2, 2007, October 31, 2007, and December 20, 2007, and for  
40                  a face-to-face meeting in Bethesda, Maryland, on November 14–16, 2007.

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

5  
6 **Draft Report Discussion**

7 *Dr. George Daston, HHRA Subcommittee Chair*

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

13  
14 Mr. Bruce Allen said that the summary was well written, and he had few comments. He  
15 suggested deleting the third paragraph on page 2 because it was repetitive with the preceding  
16 paragraph and it incorrectly referenced items in Appendices A and B. Dr. Daston agreed.

17  
18 Mr. Allen directed the Subcommittee members to the last sentence of the summary, which  
19 describes Long-Term Goal (LTG) 3. It reads, "The rating of Meets Expectations therefore should  
20 consider the above mentioned factors." He pointed out that summary statements were not  
21 repeated at the end of the discussions for the other LTGs, and he suggested removing this  
22 sentence. Dr. Daston agreed. Dr. Richard Corley remarked that he thought summary statements  
23 were listed for the other LTGs. Mr. Allen explained that a summary statement was given at the  
24 beginning of each paragraph describing an LTG, but it was not necessary to repeat the statement  
25 at the end of the paragraph.

26  
27 Mr. Allen questioned what was meant by the term "stretch goal." Dr. Daston explained that the  
28 term is common among Procter & Gamble associates; it is defined as a goal that transcends  
29 expectations. Dr. Daston said that he would rephrase this term throughout the summary.

30  
31 Mr. Allen confirmed that editorial comments could be sent to Dr. Daston and Ms. Foellmer after  
32 the teleconference.

33  
34 Dr. Mark Utell noted that the summary reflected the general opinions of the Subcommittee  
35 members. He stated that he was concerned about the balance of the LTG discussions in the  
36 summary. Recommendations pertaining to LTG 1 seemed to be disproportionately highlighted in  
37 comparison to the recommendations pertaining to LTGs 2 and 3. Dr. Utell noted that the  
38 Subcommittee members had concerns regarding LTGs 2 and 3, but these were missing from the  
39 summary. Specifically, the HHRA Program is transitioning from the criteria documents to the  
40 integrated science assessments (ISAs), and the Subcommittee members had questioned how  
41 adequately the ISAs would serve as a replacement. Dr. Daston answered that the discussions  
42 related to LTG 3 were sparse because the transition to ISAs is in its early phases, and the  
43 Subcommittee members were unable to assess the quality of the product at this point. Dr. Utell  
44 agreed that there are few ISAs available to review; nevertheless, he thought that the  
45 Subcommittee members' concerns about identifying gaps in the research and integrating old and  
46 new studies should be noted in the summary. The ISAs will inform the Agency and the public so  
47 the Subcommittee's review of these documents should be balanced with the review of LTG 1.

1 Dr. Daston clarified that the summary assessment for LTG 3 in the report body reflects  
 2 Dr. Utell’s comments, but perhaps these recommendations also should be listed in the program  
 3 quality section in the summary. Dr. Lauren Zeise stated that program quality is discussed on  
 4 page 6; she asked how Dr. Utell would suggest changing it. Dr. Utell pointed out the sentence,  
 5 “We are confident that it will continue to be of high quality.” He emphasized qualifying the  
 6 sentence to reflect the Subcommittee members’ concerns. Dr. Daston suggested changing the  
 7 sentence to, “Because of the newness of the procedure, the Subcommittee withholds judgment as  
 8 to whether this will be an improvement or an area of concern.” Dr. Utell offered to compose a  
 9 short section explicitly discussing the potential shortcomings of LTG 3. He will transmit this to  
 10 Dr. Daston and Ms. Foellmer for incorporation into the program quality section of the summary.  
 11

12 Dr. Zeise suggested that the discussion of LTG 3 acknowledge the process involved in preparing  
 13 an ISA. Stakeholders and congressional staff provide input to the ISAs, and it is unclear at this  
 14 point whether the ISAs will be considered as useful as the criteria documents. Dr. Daston  
 15 suggested inserting the language, “The Subcommittee acknowledges that it has had review by  
 16 other groups, but we still have some concern and uncertainty about the outcome from a process  
 17 that has only been tried once before.” Dr. Utell emphasized that the criteria documents were  
 18 voluminous, world-class documents, and the ISAs are a variation that may prove equally as  
 19 important. The Subcommittee members’ concerns must be voiced to ensure that the HHRA  
 20 Program recognizes potential shortcomings early in the process.  
 21

22 Dr. Utell asked for a definition of the acronym UNEP. Dr. Daston replied that it stood for United  
 23 Nations Environmental Programme. Mr. Allen pointed out that MOU, or memorandum of  
 24 understanding, also was not defined. Dr. Daston agreed to define those acronyms in the  
 25 summary. Dr. Utell suggested that a glossary of acronyms be prepared. Dr. Daston will  
 26 determine whether preparing a glossary is feasible.  
 27

28 Mr. Allen noted that on page 9, the last sentence in the first paragraph refers to a response to  
 29 Charge Question 2. He recommended amending the sentence as the reference was incorrect.  
 30 Mr. Allen specified that the sentence immediately precedes the heading for LTG 1 and refers to  
 31 information being provided by the program and regional offices. Dr. Daston will remove the  
 32 phrase “as noted in response to question 2” in this section.  
 33

34 Dr. Zeise directed the Subcommittee members to the program quality section on page 6. In the  
 35 paragraph that follows the recommendations, one sentence reads, “The extent of peer review for  
 36 [Integrated Risk Information System] IRIS and ISA assessments exceeds any other examples  
 37 with which the Subcommittee is familiar.” She suggested modifying that statement as there may  
 38 be other documents with more extensive peer review. Dr. Daston will change the phrase  
 39 “exceeds any other examples” to “exceeds most other examples.”  
 40

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

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

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

9  
10 Dr. Anderson directed the Subcommittee members to page 3 of the summary. He pointed out the  
11 sentence, "...given the complexity of IRIS reviews, that it should be considered to be an  
12 ambitious goal." He suggested changing the phrase "given the complexity of" to "given currently  
13 allocated staff and resources for." He noted that the goal is ambitious primarily because  
14 resources are lacking. Dr. Daston said that he would incorporate that change.

15  
16 Dr. Anderson noted the phrase on page 5, "in the absence of either IRIS or [Provisional Peer-  
17 Reviewed Toxicity Values] PPRTVs, a chemical may result in being inappropriately elevated in  
18 priority," does not consider the possibility that an absence of data also could inappropriately  
19 demote the priority of a chemical. Dr. Daston will change "inappropriately elevated in priority"  
20 to "inappropriately prioritized."

21  
22 Dr. Anderson confirmed that typographical corrections should be transmitted to Dr. Daston and  
23 Ms. Foellmer.

24  
25 **Public Comment**

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

27  
28 **Draft Report Discussion (Continued)**

29 *Dr. George Daston, HHRA Subcommittee Chair*

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

32  
33 **Next Steps**

34 *Dr. George Daston, HHRA Subcommittee Chair*

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

40  
41 Ms. Foellmer requested that Subcommittee members complete their homework sheets and  
42 transmit them to her for compensation.

43  
44 Dr. Daston thanked the members of the Subcommittee for their contributions and adjourned the  
45 call at 4:15 p.m.

46

1 **Action Items**

2  
3 ✧ Dr. Daston will:

- 4
- 5 • Delete the third paragraph on page 2;
  - 6
  - 7 • Delete the last sentence of the summary;
  - 8
  - 9 • Rephrase the term “stretch goal” throughout the summary;
  - 10
  - 11 • Define UNEP and MOU in the summary;
  - 12
  - 13 • Determine the feasibility of preparing a glossary of acronyms as a third appendix to the
  - 14 Subcommittee’s report;
  - 15
  - 16 • Delete the phrase “as noted in response to question 2 in this section” from page 9,
  - 17 paragraph 1;
  - 18
  - 19 • Replace the phrase “exceeds any other examples” with “exceeds most other examples” in
  - 20 the program quality section, page 6;
  - 21
  - 22 • Replace “unfortunate to remove any” with “inappropriate to remove any unless made
  - 23 irrelevant or incorrect because of data that have become available since the review” in the
  - 24 relevance section, page 3;
  - 25
  - 26 • Replace the phrase “given the complexity of” with “given currently allocated staff and
  - 27 resources for” on page 3; and
  - 28
  - 29 • Replace “inappropriately elevated in priority” with “inappropriately prioritized” on page
  - 30 5.

31  
32 ✧ Dr. Utell will compose a short section discussing the Subcommittee’s concerns about LTG 3.

33  
34 ✧ Dr. Daston will incorporate Dr. Utell’s discussion of LTG 3 into the program quality section

35 of the summary.

36  
37 ✧ The Subcommittee members will submit any corrections of an editorial or nontechnical

38 nature to Dr. Daston and Ms. Foellmer. Dr. Daston will incorporate corrections into the

39 summary.

40  
41 ✧ Ms. Foellmer will transmit the entire report, with the revised summary, to the Subcommittee

42 members.

43  
44 ✧ The Subcommittee members will review the final report. If changes of a substantive and/or

45 technical nature are warranted, the Subcommittee will reconvene for a sixth public meeting

46 to finalize the report.

47

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

## PARTICIPANTS LIST

### Subcommittee Members

**George Daston, Ph.D., Chair**  
Miami Valley Laboratories  
The Procter & Gamble Company

**Bruce Allen**  
Consultant

**Henry Anderson, M.D.**  
Chief Medical Officer for Occupational and  
Environmental Health  
Wisconsin Division of Public Health, Madison

**Richard Corley, Ph.D.**  
Center for Biological Monitoring and Modeling  
Battelle Pacific Northwest National Laboratory

**Mark Utell, M.D.**  
Pulmonary and Critical Care Unit  
School of Medicine  
University of Rochester

**Lauren Zeise, Ph.D.**  
Chief, Reproductive and Cancer Hazard  
Assessment  
Office of Environmental Health Hazard  
Assessment

### Subcommittee Designated Federal Officer

**Joanna Foellmer**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental Assessment

### EPA Participants

**James Avery, Ph.D.**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental Assessment

**Stan Barone, Ph.D.**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental Assessment

**Rebecca Clark**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental Assessment

**Andrew Gillespie**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental Assessment

**Thea Johnson**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center of Environmental Assessment

**Debra Walsh**  
U.S. Environmental Protection Agency  
Office of Research and Development  
National Center for Environmental  
Assessment

### Additional Participants

**Kurt Blaise**

**Maria Hegsted**  
Risk Policy Report

**Brian Kleinman**  
Office of Management and Budget

### Contractor Support

**Jennifer Griffin**  
The Scientific Consulting Group, Inc.



## **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	