

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

**BOARD OF SCIENTIFIC COUNSELORS
ENDOCRINE DISRUPTING CHEMICALS SUBCOMMITTEE**

**Conference Call Summary
December 1, 2004
12:00 noon – 2:00 p.m. EST**

Welcome, Overview, Introduction, and Agenda Review

Dr. Anna Harding (Oregon State University), Chair of the Endocrine Disrupting Chemicals (EDC) Subcommittee of EPA's Board of Scientific Counselors (BOSC), welcomed the Subcommittee members to their second conference call and thanked them for their participation. She stated that the purpose of this conference call is to assess group progress and review the materials received from EPA in preparation for the face-to-face meeting to be held in Research Triangle Park (RTP), North Carolina, December 13-15, 2004. She thanked Dr. Elaine Francis (EPA/ORD) and her workgroup for assembling the materials. Also during this conference call, the Subcommittee members will discuss the proposed meeting agenda and the format for the written report and address other issues that might arise.

Dr. Harding asked the participants to identify themselves and their affiliations. Dr. Neil Stiber (EPA/ORD), the Designated Federal Officer (DFO) for the EDC Subcommittee, reminded the participants of the Federal Advisory Committee Act rules and regulations detailed during the previous conference call. He mentioned the homework sheets that were distributed to the Subcommittee members and asked them to use the sheets to track the time they spend working on Subcommittee assignments outside these conference calls and the December meeting. He will collect these sheets at the December meeting in RTP, and will collect them again when the Subcommittee completes its work, probably in February 2005. Dr. Stiber informed the Subcommittee members that their airline tickets for the December meeting would be issued by EPA; the members should expect their itineraries and tickets to arrive soon. The contractor also has made reservations at the hotel in RTP; each Subcommittee member will receive a confirmation number for their reservations and will be reimbursed for hotel costs. Dr. Stiber also informed the Subcommittee members that EPA has requested Dr. Van Der Kraak (University of Guelph) to recuse himself from matters pertaining to the herbicide atrazine.¹ Dr. Harding reminded the Subcommittee members that Dr. George Daston (Procter & Gamble) would not be attending the meeting at RTP because he will be attending a meeting in Brussels.

Discussion of Meeting Materials

¹ The November 30, 2004 e-mail from Dr. Glen Van Der Kraak to Dr. Neil Stiber (BOSC-EDC Subcommittee DFO) states: "I recuse myself from participating in BOSC-EDC Subcommittee activities that concern atrazine. I will not participate personally and substantially in an official capacity in any particular matter concerning atrazine."

Dr. Harding expressed her thanks to Dr. Francis for assembling and organizing the materials sent to the Subcommittee members. She commented on the substantial amount of information, asked whether Subcommittee members found the materials to be relevant and worthwhile, and called for any questions about the materials.

Dr. George Lucier (Consulting Toxicologist) commented that despite the considerable amount of material, he found the individual abstracts, descriptions of long-term goals (LTGs), and the rest of the information to be helpful. The materials gave him a better sense of the scope of the December meeting, and were useful in pointing out additional questions that the Subcommittee might wish to address. Dr. Lucier also commented on some overlap among the abstracts in terms of the LTGs they address. He pointed out the difficulty in making distinctions, for example, between dose response and impact on human or ecological health. He asked whether, as he reads through the abstract, he should keep in mind LTGs other than the one on which he has been asked to report. Dr. Harding commented that she foresaw overlap among the goals and that it would be appropriate to write about the goals as overlapping areas of interest. Dr. Lucier acknowledged the need to categorize the abstracts for organizational purposes, but he acknowledged that the groupings are somewhat arbitrary. Dr. Harding stated that it would be best to cover the abstracts as they have been grouped by Dr. Francis and her colleagues; the assignment of abstracts to specific sections was made after significant discussion.

Dr. Lucier said it is his understanding that each Subcommittee member will review the posters under the LTG to which he/she has been assigned. Dr. Lucier stated that he would like to view posters in other sections as well in case they contain information useful to his section of the report. He asked whether other members thought this was appropriate. Dr. Stiber responded that the goal of this review was not to critique individual projects; therefore, it would be appropriate for Subcommittee members to draw information from all of the posters at the session.

Dr. Glen Boyd (Tulane University) also commented on the copious materials, agreeing that they were extremely helpful in providing him with an understanding of how all the topics fit together and helped him develop a better sense of the specific scientific questions he is to address. He asked if his packet was missing some information because there were references to additional materials that he had not been able to locate. Dr. Boyd asked specifically about a written management evaluation, completed in 2000 and updated in 2001, which identified several sources and target compounds that were examined in the risk management session. He also was unable to find a written report that summarized the outcomes of this evaluation, identifying specific sources or EDCs targeted by this group. He also asked about the proceedings from a workshop held in October 2003, which included a list of recent products generated in the risk management session. Dr. Boyd inquired about an updated list; he has a bibliography but not a categorized list of sources or products generated by this session.

Dr. Francis responded that a few items remain to be sent to the Subcommittee members; her goal is to send these out prior to the meeting. The written management evaluation is one of the remaining items; it is being edited and will be sent to members electronically before the meeting. As for the list of recent products generated during the October 2003 workshop, Dr. Francis commented that a formal list of products does not exist because research within the intramural

program, one of EPA's newest programs, has been underway for only a few years. Abstracts from this program detail ongoing efforts rather than any existing products, but she will check with the scientists in charge to determine whether any updated lists are available.

Dr. Lucier asked a question about the sequential nature of the LTGs. He commented that screening and testing are obviously meant to identify areas to review in more detail, such as chemicals, endpoints, etc. LTG2 is designed to do the same in terms of determining the impact of disrupting chemicals on human health and the environment, and LTG3 is designed to put this information in the context of a public health policy decision-making framework. He asked whether this sequence was intended by the developers of the LTGs.

Dr. Francis clarified that the research is meant to provide EPA with immediate methodologies that can be used to make decisions to accomplish the Agency's congressionally mandated activities. The LTG for improving the understanding of science really consists of a core research program that focuses on understanding mechanisms of action, pathways, and development of approaches for mediating risk. The LTG for determining the extent of impact includes research assessing tools, methods, and models under development for determining how large an impact a disrupting compound can have on the environment and/or human health.

Dr. Harding thanked Dr. Francis again for her work in assembling the meeting materials. She commented that they were very well organized and would be helpful to the Subcommittee members in completing their review.

Proposed Format for the Written Report

Dr. Harding called for comments on the proposed format for the written report. The example sent to Subcommittee members was a peer review report on EPA – NHEERL's Experimental Toxicology Division. (The cover letter for this peer review was sent by Dr. Glenn Sipes at the University of Arizona.) The first chapter of the report is an executive summary, with each subsequent chapter discussing a particular area under evaluation. Dr. Harding stated that each LTG will represent a chapter, and each chapter will have an introductory section, followed by three sections that respond to each of the three charge questions. One section will discuss program design, another will discuss relevance, and the third will evaluate program progress and performance. Strengths and challenges within each subsection also will be addressed—each charge question will have a section on strengths and challenges, and there may be specific recommendations associated with the challenges. Dr. Harding asked the Subcommittee members to comment on using this format for their report.

Dr. Daston said that he thought this format would be appropriate for the report and that it seemed to be the correct length, with no more than 3 to 5 pages to cover each of the LTGs. Dr. Harding added that the piece on leadership and resources would comprise sections 3 and 4 as separate chapters and that she and Dr. Juarine Stewart (Morgan State University) will work on these sections.

The Subcommittee members agreed that this format would be suitable for the report and that the length of the report is appropriate, approximately one paragraph for each scientific question

pertaining to each of the LTGs, with separate paragraphs on strengths and challenges. Dr. Van Der Kraak commented that Subcommittee members should be sure to point out anything they believe is missing. Dr. Lucier asked how the Subcommittee should develop recommendations. He thought that this topic should be discussed at the meeting. Dr. Harding noted that the group would have time to discuss recommendations at the meeting. In response to a question from Dr. Donald Tillitt (U.S. Geological Survey), Dr. Harding confirmed that each subcategory within an LTG would be introduced by an overview or summary of the program as it currently stands relative to that LTG.

Dr. Harding then asked subgroup leaders to comment on how their work is proceeding. Dr. Lucier, who leads the subgroup focusing on LTG2 (the group includes Drs. Van Der Kraak, Safe, and Tillitt), commented that the work will proceed more efficiently now that the members have received their information packets. He hopes to bring to the meeting a draft of the key issues and elements of the charge questions relevant to LTG2. It can be modified at the meeting. Dr. Lucier's group has assigned writing tasks by dividing the LTG into ecological and human health. Drs. Van Der Kraak and Tillitt will work on the ecological health portion, and Drs. Lucier and Safe will work on the human health portion. Because Dr. Safe could not attend this conference call, Dr. Lucier offered to send him an e-mail to inform him of the subgroup's plans.

Dr. Harding commented that when subgroups write their sections, they should clarify the charge question associated with each LTG. If these subdivisions are apparent in the writing, it will make compiling the entire report easier. She also asked that all members of the Subcommittee work in Microsoft Word.

Dr. Daston discussed the activities of his two subgroups. The first subgroup is focusing on the question regarding better understanding of the science (Drs. Tillitt, Daston, and Boyd are working on this issue). The topic has been divided into five key research areas and the subgroup members are addressing the areas pertinent to their respective fields of expertise. The second subgroup is focusing on screening and testing (Drs. Daston, Van Der Kraak, and Safe are working on this issue). This topic has been divided along the three charge questions, and each subgroup member will be responsible for reporting on one of these questions. Dr. Daston commented that the meeting materials have helped the group to refine the focus of their section of the report; they will have an outline or rough draft of the report ready by the face-to-face meeting. Dr. Daston reminded Dr. Harding that he will not be able to attend the face-to-face meeting; therefore, his group members will share their drafts among themselves and copy Dr. Harding on the e-mails. Members of these subgroups also plan to speak together on a separate conference call to work out any other logistics. In response to a question about conducting such a conference call, Dr. Stiber answered that a DFO is not needed for a call consisting only of members of the subgroup.

Dr. Stewart asked the Subcommittee members to consider resources needed to carry out each of the long-term objectives they will be writing about, which will help her to report on the distribution and adequacy of those resources (both money and personnel). Dr. Harding added that she will work on the leadership question and that many of the issues raised under each of the LTGs pertain to this question. She added that all of the Subcommittee members will be asked to review the entire report and point out any omissions.

Agenda for the Face-to-Face Meeting

Dr. Harding asked Dr. Francis to discuss the agenda for the meeting in RTP. The first session includes a welcome to participants and opening remarks. Dr. Francis will present an overview of the research program in the context of how ORD performs research planning and priority setting and also comment on issues of leadership of scientific programs. Details of the science itself will be discussed in the overviews of the LTGs. The program will begin with LTG3 because this goal has an immediate impact on the Agency. It also has the highest visibility because of the outcomes associated with it, including development of products used by EPA and the Organization for Economic Cooperation and Development. Starting with this goal will allow participants to see the connection between research activities and the specific needs of EPA. A poster session with 16 posters will follow. This session covers protocols, *in vitro* and *in vivo* research, research using model organisms, and development of computational approaches. Another series of posters will cover long-term multigenerational studies. At the end of the session, a presentation will demonstrate how the end user of the research, for example, someone at the program office or Office of Prevention, uses the data. The last poster will discuss the future, including the leveraging that the Agency has achieved with computational intelligence programs. Dr. Francis commented that a great deal of information aimed toward understanding the program will be presented on the first day.

The second day of the meeting will follow the same pattern. The day will begin with an overview of LTG1, which will be divided into two presentations because one presentation could not cover the breadth of research encompassed by this goal. Dr. Earl Gray will give a presentation titled “Improving Scientific Understanding: Effects Using Mammalian and Aquatic Models,” and Dr. Greg Sayles will present “Improving Scientific Understanding: Exposure and Risk Management Methods Development.” Dr. Greg Toth will give a third presentation on this topic Tuesday afternoon.

During each poster session, the Subcommittee members will be able to meet with the principal investigators (PIs) to ask questions about the research presented on their posters. An hour discussion session has been scheduled, and it is hoped that those serving as leads for each LTG can moderate the discussion. All the PIs will attend the discussion sessions, and this will be the time to discuss any issues that cut across LTGs or any issues that need clarification.

The last day of the meeting will include two presentations in the morning—one on who uses the research and its impact on two areas, namely, a Program Office and a Region. The second presentation of the morning will be a short summary of what has been presented during the meeting by Dr. Francis.

Dr. Harding asked about the format of the poster session. Will the posters be arranged together to allow people to move from one poster to another or will there be formal comments by each of the investigators? Dr. Francis answered that the poster presenters will not give formal presentations. She added that meeting participants will be provided small-scale copies of all the posters, along with abstracts.

Dr. Stiber explained that the poster session will be an open session during which Subcommittee members can view the posters appropriate to their particular subgroup. He noted that there will be a discussion session at which the PIs will be asked to give a 2-minute synopsis of the discussions that took place at their poster during the poster session. The PIs' synopses will summarize the contents and serve as a starting point for discussion of the posters among the entire group; in this way, the content of each poster will become part of the group discussion. Several members of the Subcommittee expressed concern that there would not be sufficient time in the poster discussion session for all the presenters to provide a summary of their posters and to allow for adequate discussion. Dr. Stiber explained that because members will have the poster content and abstracts available to them, this session can focus on any questions or issues in need of clarification that arose during the poster session. Dr. Francis added that this session will provide an opportunity for poster presenters to address any questions raised by several of the Subcommittee members.

The Subcommittee members continued to express concern that insufficient time had been allotted for an adequate discussion of all the posters presented in each poster session. The poster session for posters pertaining to LTG2 was of particular concern because this session is only 1 hour and 15 minutes and includes 16 posters. Dr. Lucier suggested that the posters be divided among the Subcommittee members so that each member can concentrate on four or five of the posters in detail. Dr. Van Der Kraak supported this suggestion, noting that it will ensure that members writing on a given LTG will have sufficient information to complete their work; an added benefit is the recognition given to poster presenters. Dr. Stiber stated that, if the Subcommittee members agree, it would be possible to extend the poster session slightly by eliminating some of the time allotted to discussion or work sessions later in the day. Dr. Francis agreed that assigning Subcommittee members to specific posters is a good plan and that members who are not working on the particular LTG covered at a given poster session might still attend the session and help review the posters. Dr. Harding agreed that such an approach would be appropriate.

Goals for Progress on the Written Report

Dr. Harding asked the Subcommittee members to discuss what they thought would be accomplished by the end of the 3-day meeting. She asked whether the members thought they would be able to present an oral report at the end of the meeting. Dr. Harding expressed doubt that a draft written report could be ready by the end of the meeting.

Dr. Daston said that he believes the presentation of an oral report is predicated on having a written report. Unless the members have enough information going into the meeting and can draft an executive summary, he does not believe they will have a consensus oral report ready by the end of the meeting. Dr. Lucier agreed that it would be necessary to have some written material on which to base the oral report to avoid inconsistencies with the written report. With approximately 2 hours to prepare an oral report, the Subcommittee would have to agree on a major issue to present or a major comment to make. The oral report would have to be limited to brief statements on particular strengths or weaknesses agreed on by all Subcommittee members. Dr. Stewart thought that the Subcommittee should be able to reach consensus on enough common strengths and weaknesses to provide an oral report that will be consistent with the

eventual written report. Dr. Harding noted that the members might add information and detail to the written report, but she agreed that the members should be able to make some general comments by the end of the meeting.

In response to a question concerning what sort of an oral report is generally provided at these meetings, Dr. Stiber responded that this Subcommittee would actually be setting a precedent. He thought that the EPA would like the Subcommittee to give some immediate feedback at the meeting, but this will depend on whether the members have adequate opportunity to deliberate and come to a consensus on what will be reported. Dr. Harding expressed concern that an immediate report would not be complete and that, as Chair of the EDC Subcommittee, she would not want to issue a draft statement that later was found to be inconsistent with what the group wished to report. Dr. Stiber emphasized that the oral report would be framed as a draft presentation and that changes would be expected. Dr. Francis confirmed that this meeting was a pilot for a series of similar meetings that will take place in the future. She also commented that she recognized that this Subcommittee had little time to prepare because of the need to schedule a meeting before the end of the year. Nonetheless, the expectation is that there will be a draft report at the end of the meeting, with the emphasis on “draft”—those reading the draft would realize that they were reading the results of discussions, without the benefit of careful writing and revision. There also is value in writing down the results of the discussion while the information presented at the meeting is still fresh in Subcommittee members’ minds.

Dr. Van Der Kraak asked whether the discussion/work session on the second day of the meeting, which was changed from 4:30 p.m. to 5:30 p.m. to allow an extra 15 minutes for the preceding poster session, could be extended to 6:00 p.m. or 6:30 p.m. to give members more time to develop the key points for the oral presentation on Wednesday. Dr. Stiber mentioned that because the meeting is announced in the *Federal Register*, the times are limited to those set in the announcement. He offered to check whether the session could be extended. He also commented that the Subcommittee members could work together informally that evening—not as a group that is deliberating together, but as subgroups.

Dr. Harding commented that her impression is that the Subcommittee members believe it is possible to have a draft oral report of the findings on Wednesday afternoon. She asked the group whether a written report, released as a draft, also could be ready that afternoon. Most Subcommittee members agreed that it would be possible to have an oral presentation for Wednesday afternoon, but thought more time would be needed to prepare a draft written report. Dr. Harding asked the Subcommittee members to remain onsite after the meeting is adjourned to work on the written report, if their travel plans allow. She stated that the Subcommittee should aim to have a draft report ready to present to the BOSC Executive Committee at the January 27-28, 2005 meeting. Another conference call for the EDC Subcommittee is planned for January 6, 2005, during which members can further discuss the written report.

Other Meeting Issues

Dr. Stewart asked whether questions concerning resource allocation could be addressed to administrators during the work session held from 2:45 to 5:30 p.m. on Monday. Dr. Stiber responded that an administrator could present information to her, but any information she

received would be public information. Dr. Francis added that she will speak about resources in her presentation.

Dr. Boyd asked whether the meeting would be recorded and summarized. Dr. Stiber answered that the meeting, as well as this conference call, will be recorded and a summary will be prepared. Dr. Harding clarified that the summary would cover the presentations and the poster discussion session, but not the poster sessions themselves.

Dr. Lucier asked whether presenters are aware that the 30 minutes allocated for presentations includes time for questions. Dr. Francis responded that the speakers are aware of this requirement and added that the Subcommittee members will receive copies of all the presentations at the meeting.

Dr. Harding again thanked Dr. Francis for her work on the meeting preparations. She also mentioned that a few questions were added to Charge Question Number 1, in section C, related to commenting on interagency collaborations. The BOSC decided that these questions should be added to all of the program reviews and would like the Subcommittee to comment on the extent to which EPA has used other agencies and other collaborations in advancing its research agenda. The Subcommittee members also should comment on any apparent impediments to collaborations with other organizations.

Dr. Francis mentioned plans for a group dinner at a restaurant on the first night of the meeting, Monday, December 13, 2004. This dinner will be open to members of the Subcommittee, presenters, managers, and the public. Dr. Stiber will send an e-mail to inform meeting attendees of the event. Dr. Francis also asked about arrangements to transport meeting attendees from the hotel to the meeting site at EPA. Dr. Stiber stated that some of the Subcommittee members are renting cars and Dr. Francis added that she will be renting a minivan. He asked that Subcommittee members coordinate their transportation among themselves. Dr. Harding indicated that the hotel will provide breakfast and there is a cafeteria across the hall from the meeting room.

Dr. Harding called for public comments. No public comments were made during the call. Dr. Harding then adjourned the conference call at 1:40 p.m.

List of Action Items

- Dr. Lucier will send Dr. Safe an e-mail to update him of the subgroup's plans for preparing a draft by the December meeting.
- Dr. Francis will try to prepare the remaining meeting materials for distribution by the BOSC to Subcommittee members prior to the meeting.
- Dr. Stiber will determine if the discussion/work session on the second day of the meeting can be extended. If not, the Subcommittee members could work together informally that evening—not as a group that is deliberating together, but as subgroups.

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