Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
March 17, 2011 Public Teleconference Meeting
Docket Number: EPA–HQ–ORD–2011–0175
HSRB Web Site: http://www.epa.gov/osa/hsrb

Date and Time:	Thursday, March 17, 2011, 1:00 p.m. – 3:00 p.m. (See *Federal Register* Notice – Attachment B)	
Location:	Via teleconference	
Purpose:	The EPA Human Studies Review Board provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Committee Members:	(See EPA HSRB Members list – Attachment A)	
Attendees:	Chair:	Sean Philpott, Ph.D., M.S.Sean Philpott, Ph.D., M.S.
	Vice Chair:	Janice Chambers, Ph.D., D.A.B.T.
	Board Members:	George C.J. Fernandez, Ph.D. Dallas E. Johnson, Ph.D. Michael D. Lebowitz, Ph.D., FCCP José E. Manautou, Ph.D. Jerry A. Menikoff, M.D. William J. Popendorf, Ph.D. Virginia Ashby Sharpe, Ph.D. Linda J. Young, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the meeting Agenda (Attachment C), unless noted otherwise in these minutes.	

INTRODUCTORY REMARKS

Mr. Jim Downing (Designated Federal Officer [DFO], Human Studies Review Board (HSRB), Office of the Science Advisor [OSA], U.S. Environmental Protection Agency [EPA or the Agency]) opened the teleconference meeting and welcomed Board members on behalf of EPA Science Advisor Dr. Paul Anastas and the Program in Human Research Ethics. He noted that the Agency appreciated the Board members' time in preparing for the meeting. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference meeting was to review the decisions made by the Board at the January 26, 2011 HSRB meeting and to finalize the Board report from that meeting.

MEETING ADMINISTRATIVE PROCEDURES

As DFO, Mr. Downing serves as the liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) requirements are met with regard to the operations of the HSRB. As DFO, he also works with the appropriate officials to ensure that all applicable ethics regulations are satisfied. Each Board member has been briefed on the provisions of the federal conflict of interest laws and has filed a standard government financial disclosure form that has been reviewed to ensure that all ethics disclosure requirements have been met. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that Board members should state their names before speaking. At the appropriate time, members of the public may provide public comments; these must be limited to 5 minutes. No individuals pre-registered to provide public comments.

Copies of the meeting materials are available on www.regulations.gov under the docket number EPA-HQ-ORD-2011-0175. According to FACA requirements, meeting minutes, including descriptions of the discussions and conclusions reached by the Board will be prepared. These minutes will be certified by the Chair within 90 days of the meeting and posted at www.regulations.gov and on the HSRB Web site.

MEETING PROCESS

Dr. Sean Philpott explained that the Board would discuss the final draft Board report, focusing on the charge questions presented to the Board at the January 2011 meeting and summarizing the Board's response. The report is intended to be a summary of the HSRB's consensus recommendations and not a detailed technical document. The Agency and study sponsors have access to detailed meeting minutes for additional information.

For each charge question, Board members would have an opportunity to raise concerns they may have about Board conclusions and rationales. Dr. Philpott requested that the HSRB focus on substantive changes to the report that directly affect the Board's recommendations. Board members should submit typographical and grammatical corrections to Dr. Philpott and Mr. Downing via e-mail and they will be incorporated into the final report.

PUBLIC COMMENTS

Dr. Philpott invited public comment on the draft January 2011 HSRB meeting report. No public comments were presented. Dr. Philpott stated that one public comment was received via e-mail in response to the *Federal Register* announcement of the Board's teleconference meeting, but because the comment does not relate directly to any of the issues under review at the January 2011 meeting, he did not read it into the record.

BOARD DISCUSSION AND DECISION ON FINAL REPORT

Assessment of Proposed Agricultural Handler Exposure Task Force (AHETF) Research Study AHE80: Determination of Dermal and Inhalation Exposure to Workers During Mixing/Loading Wettable Powders in the United States

Dr. Philpott first addressed the AHETF study to determine exposure to workers mixing and loading wettable powders. Dr. Philpott noted that the science charge to the Board had asked if the revised AHETF scenario and field study proposal AHE80 is revised as suggested in EPA's review and if the research is performed as described, is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who perform open mixing and loading of pesticide end use products formulated as wettable powders. The Board concurred with the Agency's assessment that the AHE80 study if revised as suggested in EPA's review, and if the research is performed as described, is likely to generate scientifically reliable data, useful for assessing the exposure of handlers who perform open mixing and loading of pesticide end use products formulated as wettable powders, noting that the Board raised concerns about the study design.

Dr. Linda Young raised two significant concerns, including whether the primary objective specified in lines 296-297 of the draft Board report is valid. Dr. Young pointed out that on line 262, the sentence should be revised to state, "However, two significant concerns were raised. This first concern is how the new MUs should be distributed among the proposed strata particularly to achieve the second stated goal of the research. The second concern is whether the primary objective is valid." Mr. Jeff Evans (EPA, Office of Pesticide Programs [OPP]) asked if this was a concern only with the study currently being considered, and Dr. Young responded that it was an issue with all the AHETF studies. Mr. Evans responded that this was a fundamental concern, and EPA had held many discussions with the Board about this issue previously. Dr. Young replied that a simulation study she had conducted demonstrated that everything is conditional on the study design, and there is therefore no true mean. The mean changes when the study design changes. Dr. Philpott stated that neither he, Dr. Janice Chambers, nor Mr. Downing had received the simulation study. Dr. Young had sent it to Dr. William Popendorf as part of her comments on the protocol. Dr. Popendorf responded that he had not received the simulation study either.

Dr. Chambers suggested that the way the primary objective was phrased was incorrect. The primary objective of the protocol is to obtain reliable exposure data, and how that is expressed after the fact statistically is secondary to this primary objective, she noted. Dr. Young commented that the data may be very useful still. Dr. Philpott stated that he would refer to the scenario submission, and asked Mr. Evans to comment. Mr. Evans commented that the issues under discussion were settled matters in EPA's view, and asked what the Board's position would be. He explained that EPA would need to see Dr. Young's analysis before offering a definitive response, but this also would need to be addressed with the AHETF statistician who designed the program. Dr. Philpott commented that the concern has been raised at many HSRB meetings, but perhaps had not been emphasized during more recent meetings. He noted that the protocol submission states that the "primary benchmark objective for the scenario is that a sample from the hypothetical reference sampling distribution above be of adequate size to describe selective

measures of the normalized exposure distribution with a pre-determined degree of accuracy." It mentions that the current consensus is that the estimates of the geometric mean, arithmetic mean and the 95th percentile of normalized dermal exposure need to be accurate within 3-fold of the actual population value. Nothing is mentioned in terms of confidence. Dr. Dallas Johnson suggested that this perhaps was the problem. When calculating the geometric and arithmetic means and the 99th percentile, these are characteristic of the sample, and not characteristic of any population. Dr. Johnson recommended to remove the words "with 95% confidence" from line 297 of the draft Board report. Later in the same paragraph, it states that a population is not defined. Dr. Philpott agreed that this suggestion had merit because in reviewing the actual submission to the Agency, nowhere in the description of the primary objective does it mention 95 percent confidence. Dr. Young agreed that this would be a helpful change, but it still is not clear what these data are providing an estimate of. Dr. Johnson responded that the estimate had to be the geometric mean, the arithmetic mean and the 95th percentile exposure of the data generated. Dr. Young forwarded her simulation study to all Board members.

Dr. Philpott asked how the HSRB wanted to address the suggestions in the recommendations and rationale in a way that is informative to the Agency as it moves forward and in conversations with the protocol sponsor. He asked whether these concerns are significant enough that it would be recommended that the protocol should not go forward at this time. Dr. Johnson stated that the protocol should go forward, but caution should be taken as to what the numbers represent and how they can be used. Dr. Young added that the layout of the study is not in question, but the intention of the analysis of the study is in question, and the primary objective as stated should be reconsidered. Dr. Philpott noted that there were different places in the protocol in which the phrase "primary objective" occurred. On page 23 of 403 of the submission for HSRB review, under sample sizes it discusses primary objectives for the benchmark. It states, "estimates of the geometric mean, the arithmetic mean, and the 95th percentile of normalized dermal exposure generally need to be accurate to within approximately 3-fold of their actual population value assuming the reference random sampling model applies." On page 48 of that same document, Dr. Johnson noted that "95 percent of the time" was stated.

Dr. Johnson suggested a revision to line 296 of the draft HSRB report: "The primary objective is to estimate the geometric mean, the arithmetic mean and the 95th percentile of exposure within 3-fold of the data generated." Dr. Philpott noted that more must be provided to the Agency so that the issue can be considered and appropriate consultations with the sponsors can be conducted. Dr. William Popendorf suggested that the next sentence (line 297) contain the word "however." Dr. Philpott stated that the sentence would read, "To be meaningful, however, the population for which these quantities are being estimated must be clearly defined." Dr. George Fernandez noted that as long as the distribution of the population was considered, the data can be used as exploratory points. Dr. Young thought that the data could be used for the proportionality assumption, the secondary objective. Perhaps the secondary objective should become primary. The measure being used as the primary objective needs to be rethought, she added. Dr. Popendorf noted that the whole concept was based on the premise of having the sample; everything that was stated about the impact of the sample on the results is true, but there is no way to solve this without another study to establish that population, which is not feasible.

Dr. Philpott commented that line 302 states, "Because the sample mean depends heavily on the design, the validity of this objective is questionable." He suggested that questionability of the primary objective should be acknowledged and recognized as a limitation in the data analysis. He suggested that the last sentence of the paragraph could read, "Because the sample mean depends heavily on the design, the validity of this primary objective is questionable, and the limitations of this objective need to be considered in the use of these data." Dr. Young added that the problem being addressed is that there is a population mean, and the sample mean depends on the design, which is a major flaw in terms of using the sample mean as the population mean, and working with a geometric mean or arithmetic mean is going to be problematic. Dr. José Manautou asked whether this point made the primary objective questionable rather than dependent on the way that the study is designed. Dr. Young believed it to be questionable because the objective is flawed. Dr. Chambers noted that this implies that the entire protocol is flawed. Dr. Philpott suggested that the issue might be semantic, and a word other than "questionable" would be useful. Mr. Evans commented that he understood the problem and appreciated the Board's frustration. The word "questionable" is problematic for EPA; perhaps "limitations of the study design" could be used and would greatly benefit the Agency's ability to continue working with the AHETF. Dr. Young suggested adding the phrase "the primary objective may need to be revised." Mr. Matthew Crowley (EPA, OPP) stated that EPA did not want the AHETF to simply collect 25 measurements. The primary objective was to put some benchmark on the exposure measurements. The benchmark was meant to create an accuracy objective as a goal for the data set. Mr. Crowley noted that the problem was with the applicability, and using it as a representation of the population; EPA recognizes the limitations in this matter. EPA did its best with the sample design proposed by the task force to make the sample as representative as possible, so he is curious as to how the primary objective could be revised. It helps to make some guess as to how accurate the measurements are believed to be.

Dr. Philpott noted that the primary objective is meant to establish an accuracy benchmark for the task force, and that is a benchmark that the Board finds may not be achievable because the measures are heavily dependent on the study design. Dr. Philpott suggested that line 302 read, "because these measures depend heavily upon the design, the primary objective may not be achievable, and the limitations imposed by the study design need to be considered carefully when using the data." Dr. Chambers commented that the primary objective should not translate into a geometric mean, it should be to get an accurate range of exposures for the population. Dr. Young agreed. Dr. Chambers added that the verbiage needed to be better in the future, and should not refer to something like the geometric mean as the primary objective. Dr. Young agreed that this should be part of the HSRB's recommendations. Dr. Philpott stated that the Board was recommending that the primary objective as currently stated in the protocol may not be achievable, and the limitations imposed by the study design should be considered carefully when using the data. Additionally, the Board recommended that the primary objective be rephrased to achieve the goals that the Agency and the study sponsor intended. He asked Dr. Young how she would write the primary objective, and she deferred to Dr. Johnson's proposed wording. Dr. Chambers suggested that it was not the Board's place to restate the primary objective, but in the future, anyone writing a protocol needs to take more care with its wording. Dr. Philpott held that some guidance could be provided as to how the sponsors may want to frame the primary objective given that it is meant to ensure the accuracy of the exposure measurements. Dr. Johnson suggested that a better primary objective might be to try to estimate

the range of exposures that users would be exposed to in applying these types of chemicals with different amounts of active ingredient handled. Dr. Young stated that the primary objective is to get some measure of the range. Dr. Philpott suggested revised text to reflect that the primary objective is to "obtain a measure of the range of exposures that agricultural handlers applying pesticides as wettable powders might experience." Mr. Downing added that this point also is germane to other studies that the AHETF is conducting. Dr. Johnson added that calculating the geometric mean and other measures could be conducted, but should not be included in the protocol. Dr. Philpott suggested that the sentence to be added after line 303 read, "The primary objective of the study might better be stated as 'to measure the range of exposures that agricultural handlers who perform open mixing and loading of pesticide end-use products formulated as wettable powders' might experience." Dr. Popendorf noted that there are hazards in rewriting the objective for the study sponsors. Another way to handle this issue might be to change line 302 to read "Because the sample mean depends heavily on the design, the applicability of the primary objective to characterize the universe of handlers is limited by the representativeness of the sample population." Dr. Chambers agreed that the HSRB should not restate the protocol's objective.

Dr. Philpott noted that line 302 will be revised to read, "Because these measures depend heavily on the design, the primary objective as currently stated in the protocol may not be achievable, and the limitations imposed by the study design should be considered carefully when using the data." The HSRB agreed with the use of that wording, and that the Board would not provide additional guidance as to how the primary objective might be better phrased. Dr. Chambers suggested that the HSRB would see different primary objectives in the future following this discussion. Dr. Philpott agreed, and noted that because the sponsors and EPA would have access to detailed meeting minutes, even though the Board is not recommending specific rephrasing, they would be considering the discussion held at this teleconference meeting. The paragraph on line 296 was revised to state, "The primary objective is to estimate the geometric mean, the arithmetic mean, and the 95th percentile of exposure within 3-fold of the data generated. To be meaningful, however, the population for which these quantities are being estimated must be clearly defined." Dr. Young suggested removing the phrase "of the data generated" and the HSRB agreed. There were no further comments on the detailed response to the science charge question.

Dr. Philpott explained that the ethics charge question for this protocol asked whether the research is likely to meet the applicable requirements of 40 Code of Federal Regulations (CFR) Part 26, subparts K and L, if the revised AHETF scenario and field study proposal AHE80 is revised as suggested in EPA's review and if the research is performed as described. The Board concluded that the protocol, if modified in accordance with EPA and HSRB recommendations, is likely to meet the applicable requirements. The HSRB provided a number of suggestions as to how the study protocol should be modified. Specifically, the Board noted that the protocol should specify that potential study participants will be asked about what they normally wear when handling pesticides in a way that does not direct them to a particular answer or lead them to agree to wear less personal protective equipment than they normally would out of a desire to participate in the research. There were some concerns about language used in the consent form about refusing medical treatment; and there were some concerns about the AHETF's plan for providing exposure information to subjects who might not speak English or who have low levels

of literacy. The Board suggested how to incorporate guidance from the U.S. Department of Health and Human Services on low literacy. There were some additional recommendations, including that the requirement for additional pregnancy tests be clarified throughout the documents. Dr. Philpott asked if there were Board concerns about these recommendations. Dr. Jerry Menikoff noted that the report as it stood was fine. No other Board members had comments on the recommendation or detailed rationale in the report.

Assessment of Completed AHETF Research Studies AHE55, AHE56, AHE57, AHE58 and AHE59: Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Closed Cab Equipment

Dr. Philpott explained that the AHETF's study presented five agricultural handler exposure scenarios of closed cab airblast application of liquid pesticides. During the January 2011 HSRB meeting, the Board was asked to address two science charge questions: the first asked whether the research reported in the AHETF completed monograph report and associated field study reports was faithful to the design and objectives of the protocol, standard operating procedures (SOPs) and governing documents. The second asked if the Agency had adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating exposure of those who apply conventional pesticides with closed cab airblast equipment. The Board concurred in part with EPA's assessment, namely that the research reported in the completed monograph, associated field study reports and supplemental documents was conducted in a manner that was reasonably faithful, to the extent possible under field conditions, to the design and objectives of the protocol and governing documents of the task force. The Board also concluded that the Agency has not completely considered the limitations on these data that should be considered before using the data to estimate the dermal and inhalation exposure of those who apply conventional pesticides with closed cab airblast equipment. Additional limitations and concerns have been identified by the Board, and conclusions as to the generalizability of these data require further consideration and analysis.

Dr. Popendorf expressed concern with the fourth paragraph under the rationale section of the draft Board report, which may be one of the main concerns in the summary as well, which states (lines 714 to 716), "The data may not be an accurate reflection of the potential exposure to pesticides by agricultural workers using closed cab airblast pesticide application equipment, mainly because of the impact of the incidental exposures." That sentence is a prelude to more details; he had a concern because the Board had held a long discussion on incidental exposures, and his sense is that the incidental exposures were the primary cause of the exposures; this is not a direct limitation of the study. The data do reflect accurately the exposures of applicators in this setting. Dr. Philpott responded that the primary issue was that incidental exposures likely will be a common source of exposures, but that the study was not designed to accurately record them. Therefore, whether the data as collected could be used to accurately estimate the range of exposures of the workers was in question. Dr. Chambers noted that the Board is assuming that the lack of proportionality is due to the somewhat random incidental exposures, but that was not catalogued in any way to characterize that, so it is an assumption at this point. Dr. Popendorf added that the limitation is that the exposures were not recorded, but the fact that they occurred

was an accurate representation of the real-world scenario. Dr. Chambers agreed, but noted that no cause and effect was documented.

Dr. Philpott suggested that the concern may be semantic, and is about how the phrase "an accurate reflection of potential exposure to pesticides" is being interpreted. The question is whether the sentence accurately conveys what the HSRB intended it to mean. The data as collected may not really reflect the real-world range of exposures that occur because of the incidental exposures and the fact that they were not uniformly catalogued across all five studies. Dr. Michael Lebowitz commented that the sources of possible exposure always need to be considered throughout the exposure assessment and these were not recorded. He noted that it is a real-world situation; if it was stated that "the data collected do not reflect the full sources of exposure and thus may not represent the true exposures to these workers," that would accurately reflect the Board's concerns.

Dr. Manautou stated that the data should be an accurate reflection of actual occupational exposure. The issue is that the incidental exposure is a deviation from the study design that was not corrected for.

Dr. Philpott suggested a potential sentence that may address some of the Board's concerns. The sentence could read, "The data collected may not be an accurate measure of all of the potential sources of exposure to pesticides by agricultural workers using closed cab airblast pesticide application equipment, mainly because of the impact of the incidental exposures, which were not uniformly recorded across all five studies." The point is that the incidental exposures were not recorded for all the monitoring units, and whether that means that the data that they collected do not reflect real-world exposures. Dr. Popendorf commented that the term "measured" exposure means to him the results of the chemical analysis. Perhaps Dr. Lebowitz means observations of contact and other measurements of contaminated surfaces. Dr. Lebowitz answered that in the same way that inhalation and dermal monitoring devices are used; there must be something to measure when individuals are incidentally exposed in the field. Dr. Chambers suggested that "may not be an accurate measure of" be changed to "may not accurately account for." Dr. Popendorf noted that exposures were measured, but researchers did not account for how they occurred. Dr. Philpott suggested that the sentence be changed to, "The data collected may not accurately account for all of the potential sources of exposure to pesticides by agricultural workers using closed cab airblast pesticide application equipment, because the impact of the incidental exposures were not uniformly recorded across all five studies." Dr. Chambers commented that this statement complicates the issue. The study was not designed to catalog and account for all the different sources; the researchers wanted an overall exposure level that would include the protected people as well as the ones that have the incidental exposures. Dr. Philpott noted that this was an important issue, because some of the researchers did record the incidental exposures, and the Agency began to explore those incidental exposures as a potential source of contamination to explain why they were not seeing proportionality in the dermal exposure.

Dr. Chambers suggested that "lack of uniformity in the observations of incidental exposures" be used. Dr. Popendorf added that some exposures were not measured at all. Dr. Philpott recommended, "The data collected may not accurately account for all of the

potential sources of exposure to pesticides by agricultural workers using closed cab airblast pesticide application equipment. For example, the impact of incidental exposures was not uniformly recorded across all five studies." That provides an example of why there may be unmeasured exposures, but without necessarily attributing them to be the primary cause for the lack of proportionality. Dr. Johnson stated that no legitimate inferences could be made from the data on incidental exposures. Dr. Lebowitz noted that the incidental exposure measurement methods should have been included in the protocol, and commented that what were being referred to as incidental exposures, are in fact part of the exposure scenario in a real-life situation. They are only 'incidental' because measuring them was not part of the protocol. Dr. Philpott recognized Dr. Lebowitz's suggestion that the Agency and sponsors may want to consider how to measure these exposures in future protocols, but agreed with Dr. Chambers' concerns that the Board does not want to complicate things, and was unsure whether this was a recommendation that the Board should make on a completed study. If the HSRB were examining a proposed scenario with a potential for a great deal of exposure being attributed to unmeasured sources of exposure, the Board should make a recommendation at that time.

Dr. Philpott noted that the sentence in question will be changed to read, "The data collected may not accurately account for all of the potential sources of exposure to pesticides by agricultural workers using closed cab airblast pesticide application equipment," and the consensus of the Board is that will suffice because incidental exposure is discussed in detail later in the report. Dr. Chambers agreed with Dr. Lebowitz that use of the term 'incidental exposure' may not be appropriate because the exposures are not truly incidental. Workers will brush against the cab, for example, in real life, but the unpredictability of how much that occurs is what eliminated the proportionality relationship. Dr. Philpott responded that the words "incidental exposures" are from the protocol and monograph, so that is how the AHETF had characterized these exposures. Dr. Lebowitz suggested that the word "incidental" be placed in quotation marks. Dr. Philpott noted that "incidental," when used by the Board, could be placed in quotation marks and followed by the statement "as defined in the AHETF monograph."

Dr. Philpott stated that the fourth paragraph in the detailed recommendations and rationale (lines 712 to 719) had been modified not to refer to incidental exposures, but just failure to account for all the potential sources of exposure to pesticides.

In the paragraph starting on line 729, Dr. Popendorf noted that on line 735, the HSRB stated, "The data also indicate that the protocol did not measure incidental exposures to pesticide." Dr. Philpott replied that this had been changed based on prior comments from Board members, and will now read, "The data also indicate that the protocol did not record or report all of the activities of sources of 'incidental exposures' (as defined in the AHETF monograph) to pesticide such as contaminations occurring outside the cab in a manner that yielded good correlations with measured exposures that would have been helpful in interpreting this exposure assessment." Board members had no further comments on the science recommendations and rationale.

The ethics charge question asked whether available information supports a determination that the study was conducted in substantial compliance with 40 CFR part 26, subparts K and L. The Board concurred with the Agency's assessment that the study was conducted in substantial

compliance with the applicable requirements. The Board provided a detailed explanation about the protocol deviations that were reported by the sponsor as well as the unreported ones that the Agency identified in its ethics review. There were no further Board comments on the ethics recommendations and rationale.

Dr. Philpott noted that he would make the agreed upon changes and submit the final report to the Agency. A vote was taken to approve the final report with changes as discussed during the teleconference meeting; all members present agreed to accept the report if amended as discussed.

SUMMARY AND NEXT STEPS

Mr. Downing thanked members for a successful meeting and their diligent work on the report draft. He noted that the next face-to-face HSRB meeting would be held on April 13 and 14, 2011. The meeting will be held in Arlington, Virginia, at the Holiday Inn National Airport. The agenda has not been set for that meeting; Mr. Downing will distribute more details when they are available.

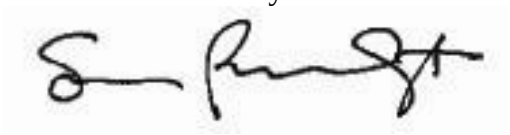
Dr. Philpott noted that the April meeting agenda would include review of a published study of nano-silver, and the Board will revisit its recommendations made previously regarding a published study by Kisicki et al because additional information was received from the sponsor that answers some of the questions in the final report from the June 2009 HSRB meeting.

Dr. Philpott thanked Board members for their participation. The teleconference meeting was adjourned by the Chair at 2:35 p.m.

Respectfully submitted:

Jim Downing
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:



Sean Philpott, Ph.D., M.S. Bioethics
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference meeting reflect diverse ideas and suggestions offered by Board members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect definitive consensus advice from the Board members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final report prepared and transmitted to the EPA Science Advisor following the public meeting.

Attachments

Attachment A	HSRB Members
Attachment B	Federal Register Notice Announcing Meeting
Attachment C	Meeting Agenda

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

*Sean Philpott, Ph.D., M.S. Bioethics — Term: 3/27/2006-10/31/2011
Director, Research Ethics
The Bioethics Program
Union Graduate College-Mt. Sinai School of Medicine
Schenectady, NY

Vice Chair

*Janice Chambers, Ph.D., D.A.B.T. — Term: 3/27/2006-10/31/2011
William L. Giles Distinguished Professor
Director, Center for Environmental Health Sciences
College of Veterinary Medicine
Mississippi State University
Mississippi State, MS

Members

*George C.J. Fernandez, Ph.D. — Term: 5/1/2010-8/31/2013
Director, Center for Research Design and Analysis
University of Nevada – Reno
Reno, NV

*^Vanessa Northington Gamble, M.D., Ph.D. — Term: 10/19/2009-10/31/2012
University Professor of Medical Humanities
The George Washington University
Washington, DC

*^Sidney Green, Jr., Ph.D., Fellow ATS — Term: 10/19/2009-10/31/2012
Department of Pharmacology
Howard University College of Medicine
Howard University
Washington, DC

*Dallas E. Johnson, Ph.D. — Term: 8/31/2007-8/31/2013
Professor Emeritus
Department of Statistics
Kansas State University
Manhattan, KS

*Michael D. Lebowitz, Ph.D., FCCP — Term: 3/27/2006-8/31/2012
Retired Professor of Public Health
(Epidemiology) & Medicine & Research Professor of Medicine
University of Arizona
Tucson, AZ

*José E. Manautou, Ph.D. — Term: 5/1/2010-8/31/2013
Associate Professor of Toxicology
Department of Pharmaceutical Sciences
School of Pharmacy, University of Connecticut
Storrs, CT

Jerry A. Menikoff, M.D. — Term: 3/27/2006-8/31/2012
Director, Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

*^Rebecca T. Parkin, Ph.D., M.P.H — Term: 10/1/2007-8/31/2013
Professorial Lecturer (EOH)
School of Public Health and Health Services
The George Washington University
Washington, DC

*William J. Popendorf, Ph.D. — Term: 10/19/2009-10/31/2012
Professor Emeritus
Department of Biology
Utah State University
Logan, UT

Virginia Ashby Sharpe, Ph.D. — Term: 5/1/2010-8/31/2013
National Center for Ethics in Health Care
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

*Linda J. Young, Ph.D. — Term: 3/28/2008-8/31/2012
Department of Statistics
Institute of Food and Agricultural Sciences
University of Florida
Gainesville, FL

*Special Government Employee (SGE)
^Not in attendance at the March 17, 2011 teleconference

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[Federal Register Volume 76, Number 40 (Tuesday, March 1, 2011)]
[Notices]
[Pages 11240-11242]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2011-4633]

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2011-0175; FRL-9274-5]

Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Draft Report From HSRB Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U. S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a public teleconference of the HSRB to discuss its draft report from the January 26, 2011 HSRB meeting.

DATES: The teleconference will be held on Thursday, March 17, 2011 from approximately 1 p.m. to approximately 3 p.m. Eastern Time.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2011-0175, by one of the following methods:

Internet: http://www.regulations.gov: Follow the on-line instructions for submitting comments.

E-mail: ORD.Docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center (EPA/DC), ORD Docket, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW., Washington, DC 20460. The hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566-1744 or e-mail the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the Web site (http://www.epa.gov/epahome/dockets.htm).

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2011-0175. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comments includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any members of the public who wish to receive further information should contact Jim Downing at telephone number: (202) 564-2468; fax: (202) 564-2070; e-mail address: downing.jim@epa.gov, or Lu-Ann Kleibacker at telephone number: (202) 564-7189; fax: (202) 564-2070; e-mail address: kleibacker.lu-ann@epa.gov; mailing address: Environmental Protection Agency, Office of the Science Advisor, 8105R, 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb/.

SUPPLEMENTARY INFORMATION:

Location: The meeting will take place via telephone only.

Meeting access: For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for providing public input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in section I, "Public Meeting," under subsection D, "How May I Participate in this Meeting?" of this notice.

I. Public Meeting

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I access electronic copies of this document and other related information?

In addition to using regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue, NW., Washington, DC 20460. The hours of operation are 8:30 a.m to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566-1744, or e-mail the ORD Docket at ord.docket@epa.gov for instructions. Updates to the Public Reading Room access are available on the Web site (http://www.epa.gov/epahome/dockets.htm).

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you use that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

D. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2011-0175 in the subject line on the first page of your request.

1. *Oral comments*. Requests to present oral comments will be accepted up to March 10, 2011. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to Jim Downing or Lu-Ann Kleibacker under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, March 10, 2011, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official (DFO) to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. *Written comments*. Submit written comments prior to the meeting. For the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your

comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, March 10, 2011. You should submit your comments using the instructions in section I, under subsection C, "What Should I Consider as I Prepare My Comments for EPA?". In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App.2 Sec. 9. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through EPA's Science Advisor.

1. *Topics for Discussion*. The HSRB will be reviewing its draft report from the January 26, 2011 HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the January 26, 2011 HSRB meeting can be found at [**Federal Register** Volume 76, Number 8 (Wednesday, January 12, 2011)] [Notices] [pages 2107-2109] and at the HSRB Web site http://www.epa.gov/osa/hsrb/. The January 26, 2011 meeting draft report is now available. You may obtain electronic copies of this document and certain other related documents that might be available electronically from the http://www.regulations.gov website and the HSRB Internet home page at http://www.epa.gov/osa/hsrb/. For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: February 25, 2011.

Paul T. Anastas,
EPA Science Advisor.
[FR Doc. 2011-4633 Filed 2-28-11; 8:45 am]
BILLING CODE 6560-50-P

Attachment C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING
AGENDA

Thursday, March 17, 2011
1:00 pm - 3:00 pm (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE DRAFT JANUARY 26, 2011 HSRB MEETING REPORT

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA–HQ–ORD–2010–0175

1:00 PM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer, HSRB, Office of the Science Advisor, EPA)
1:10 PM*	**Meeting Administrative Procedures** – Jim Downing (DFO)
1:15 PM	**Meeting Process –** Sean Philpott, Ph.D. (HSRB Chair)
1:20 PM	**Public Comments**
1:30 PM	**Board Discussion and Decision on Final Report –** Sean Philpott, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the January 26, 2011 meeting.

Agricultural Handler Exposure Task Force (AHETF) report of a completed scenario monograph and study reports of five field studies measuring the dermal and inhalation exposure of workers applying liquid spray pesticides to tree or trellis crops using closed cab airblast equipment.

Charge to the Board:

- Was the research reported in the AHETF completed monograph report and associated field study reports faithful to the design and objectives of the protocol, standard operating procedures and governing documents?
- Has the Agency adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating exposure of those who apply conventional pesticides with closed cab airblast equipment?
- Does available information support a determination that the studies were conducted in substantial compliance with subparts K and L of 40 CFR part 26?

Agricultural Handler Exposure Task Force (AHETF) scenario design and associated protocol describing proposed research to monitor exposure of workers who mix and load pesticides formulated as wettable powders.

Charge to the Board:

If the revised AHETF scenario and field study proposal AHE80 is revised as suggested in EPA's review and if the research is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who perform open mixing and loading of pesticide end use products formulated as wettable powders?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

2:55 PM **Summary and Next Steps –** Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (DFO)

3:00 PM **Adjournment**

*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: downing.jim@epa.gov.