Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
March 28, 2012 Public Teleconference/Webinar Meeting
Docket Number: EPA–HQ–ORD–2012–0175
HSRB Web Site: http://www.epa.gov/osa/hsrb

Committee Members: (See EPA HSRB Members list – Attachment A)

Date and Time:	Wednesday, March 28, 2012, 2:00 p.m. – 4:00 p.m. (See *Federal Register* Notice – Attachment B)	
Location:	Via teleconference and Webinar	
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.	
Attendees:	Chair:	Sean Philpott, Ph.D., M.S. Bioethics
	Vice Chair:	Rebecca T. Parkin, Ph.D., M.P.H.
	Board Members:	Janice Chambers, Ph.D., D.A.B.T. Jewell H. Halanych, M.D. Dallas E. Johnson, Ph.D. 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.	

COMMENCEMENT OF PUBLIC MEETING

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 Agency]) opened the teleconference/webinar meeting and welcomed Board members on behalf of EPA. He noted that the Agency appreciates the Board members' time and diligence in the meeting preparation and deliberations. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference/webinar meeting was to review the decisions made by the Board at the January 26, 2012 HSRB meeting and to finalize the Board's 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) provisions 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. At the teleconference/webinar meeting, the Board reviewed the draft final report from the January 2012 meeting, and finalized the report for submission to the Science Advisor and the Agency. Copies of the meeting materials, supporting documents and public comments are available at http://www.regulations.gov under docket number EPA-HQ-ORD-2012-0175 and most are available on the HSRB website at http://www.epa.gov/osa/hsrb. The draft final report was displayed, reviewed and modified on the website at https://epa.connectsolutions.com/hsrbtele during the teleconference/webinar. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that participants 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.

According to FACA requirements, meeting minutes will be prepared, including descriptions of the discussions and conclusions reached by the Board. These minutes will be certified by the Chair within 90 days of the meeting and posted at http://www.regulations.gov and on the HSRB website.

Prior to the meeting's commencement, Dr. Warren Lux announced to the Board that this would be his last HSRB meeting as the Director of EPA's Human Research Ethics Program. Mr. Lux expressed appreciation to the HSRB members, remarking that the HSRB has achieved widespread national respect and credibility among virtually all stakeholders. The HSRB Chair, Dr. Sean Philpott, expressed warm wishes for Dr. Lux's future endeavors and noted that it had been a pleasure to work with him.

MEETING PROCESS

Dr. Philpott took roll to determine which members were present on the call; the quorum of seven was met. He thanked the Board members for their diligent work at the January 2012 meeting and in completing their sections of the meeting report, and thanked the Agency staff for their assistance and comments. The goal of this meeting was to review and finalize the meeting report from the January 26, 2012 HSRB meeting. He explained that the Board would discuss the draft HSRB meeting report, focusing on the charge questions presented to the Board and the HSRB's recommendations. He noted that comments received from HSRB members and Agency staff had been incorporated into the report and would be indicated by Dr. Philpott as the Board discussed the draft report. Dr. Philpott also stated that he would identify one question that remains open for consideration based on comments received from the Agency. For those participants who were able to log in to the webinar, Dr. Philpott modified the draft report document directly in real time. Dr. Philpott referred to page and line numbers where changes were incorporated. Dr. Philpott stated that 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.

The agenda for the teleconference/webinar included the completed Agricultural Handler Exposure Task Force (AHETF) research on mixing, loading and applying liquid pesticides and the Antimicrobial Exposure Assessment Task Force II (AEATF) study of the application of a liquid pesticide product using an aerosol can. Board members had an opportunity to raise questions and concerns that they had about the Board's 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 were directed to submit typographical and grammatical corrections to Dr. Philpott and Mr. Downing via email so that they could be incorporated into the final report.

BOARD DISCUSSION ON THE FINAL REPORT

Assessment of Proposed AHETF Research Study AHE-600: Mixing, Loading and Applying Liquid Pesticides in Managed Horticultural Facilities Using Powered Handgun Equipment

Dr. Philpott addressed the AHETF study, which was designed to determine exposure during mixing, loading and application of liquid pesticide sprays using powered handgun equipment. He noted that the science charge to the Board, starting on line 275 of the draft report, asked if the AHETF proposal 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 workers mixing, loading and applying pesticides in managed horticultural facilities using powered handgun equipment. The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Evans, Sarkar and Sherman 2011) and HSRB recommendations, is likely to generate high-quality, reliable and useful data for assessing worker's pesticide exposures in horticultural settings. The Board provided several additional comments or suggestions with respect to the use of personal protective equipment, the potential effect of unanticipated incidental exposures and other variables on proportionality, and the utility of existing European Crop Protection Association data.

Dr. Philpott noted one change made to the teleconference document on line 311. Mr. Tim Leighton (EPA, Office of Pesticide Programs [OPP]) had pointed out that the Board misstated the objective of the study. Dr. Philpott added to the document the primary objective of the study based on what is written in the EPA Science Review, changing the text to read: "The primary objective is to estimate the geometric mean, arithmetic mean and the 95th percentile of normalized dermal exposure for agricultural workers who mix, load and apply pesticides in nurseries or greenhouses using a hand-held sprayer or gun. A secondary objective is to demonstrate proportionality between the amount of active ingredient handled (AaiH) and exposure level."

The draft report noted that the Board had discussed the use of respirators and half masks in the scenario and how to adjust the skin exposure data relative to the proportion of the head and neck covered by the respirator. At the January 2012 meeting, the Board perceived that this issue was not stated in the protocol documents or EPA's review of the protocol. Mr. Matthew Crowley

(EPA, OPP) commented that the AHETF's standard operating procedure (SOP) 9.K.0 provides information to this effect. Thus, Dr. Philpott added one sentence starting on line 346 to read, "After the conclusion of the January 2012 meeting, however, it was pointed out to the Board that the AHETF's SOP 9.K.0 provides information about how measured skin exposure to the face will be adjusted upward in proportion to the area of the face/neck covered by a respirator." Mr. Crowley also had commented that, contrary to line 349 of the original report, EPA does not intend to test any variables except for the AaiH. That modification was incorporated into the document accordingly while still noting variables that can affect the proposed exposure data. Dr. Jewell Halanych noted that one variable discussed in the meeting but missing from the list starting on line 353 was whether the monitoring unit was walking or riding in a motorized vehicle; Dr. Philpott added that variable to the list. He solicited additional concerns, clarifications or questions from the Board, reminding Board members that he is requesting substantive comments and not editorial corrections.

Dr. Janice Chambers recalled that during the January meeting, Dr. William Popendorf was concerned by the use of the term "incidental." Dr. Philpott clarified for the Board that the concern arose from a discussion between Dr. Popendorf and Dr. Michael Lebowitz about how the term "incidental" can be used. He noted that the Board has been using "incidental" in the same way that the Agency has been using the word in its documents. Dr. Philpott was willing to change "incidental" to "unanticipated" within the draft report, but he asked whether or not Board members felt that it changed the substantive nature of the document. Dr. Chambers asserted that it was not a substantive change, unless there was a technical difference in how the term is used. Dr. Popendorf explained that his concern was that the issue had to do with exposure to residues from a prior application, such as leaning on the spray equipment. These exposures are not directly related to the application being studied. He continued, noting that as long as it was clear in the report what the word "incidental" was referred to, he did not have an issue. Dr. Philpott replied that around line 314 of the draft report, the Board gave the explanation that because of the proximity of sprayed plants, workers were likely to experience unintended exposure. The document went on to state that, "In scenarios where unanticipated incidental exposures are likely to occur, it will be important for researchers to observe and document all unintentional contacts with treated plants or other events that might contribute to the exposure levels." Dr. Philpott asked whether that language articulated Dr. Popendorf's concerns, and if not, what changes he would suggest to clarify the substantive nature of the issue. The issue was tabled to allow Dr. Popendorf time to access the webinar.

The issue regarding the use of the word "incidental" in respect to describing exposures was revisited at the termination of the call. Upon reconsidering the text, Dr. Popendorf stated that although the language is not as specific as he would prefer, he would approve. Defining the term more clearly, he thought, might be more appropriate for discussion at another time. Dr. Philpott remarked that the Board members had intentionally limited the use of "incidental" in drafting the report, and he can replace all remaining instances with the word "unanticipated." Dr. Popendorf agreed that replacing "incidental" with "unanticipated" was acceptable.

Dr. Philpott solicited additional concerns regarding the science charge to the Board. Ms. Kelly Sherman (EPA, OPP) was concerned because EPA had suggested a few additional edits that had not been mentioned by Dr. Philpott, who responded that he had made those edits

but had not identified them specifically during the meeting because they were primarily editorial (e.g., typographical errors and word substitutions) and not substantive in nature.

The ethics charge to the Board begins on line 395 and reads: "If the AHETF proposal is revised as suggested in EPA's review and if the research is performed as described, is the research likely to meet the applicable requirements of 40 Code of Federal Regulations (CFR) Part 26, subparts K and L?" The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Evans, Sarkar and Sherman 2011) and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L. Dr. Philpott noted that there were no substantive comments on the draft report, most of the recommendations are concordant with the Agency's report, and the suggested changes to the informed consent and other materials were documented. There were no additional member concerns or comments about the recommendations or detailed rationale for the ethics charge question.

PUBLIC COMMENTS

Dr. Philpott noted that he had made an error in the administrative procedures of the meeting by neglecting to invite public comments prior to starting the discussion of the final report. Although Mr. Downing had noted that there were no pre-registered individuals, time was available for public comments. Dr. Philpott invited participants to comment publically on the draft January 2012 HSRB meeting report. No public comments were presented.

BOARD DISCUSSION AND DECISION ON THE FINAL REPORT

Assessment of Completed AEATF II Research Study AEA-04: Measurement of Potential Dermal and Inhalation Exposure During Application of a Liquid Antimicrobial Pesticide Product Using a Pressurized Aerosol Can for Indoor Surface Disinfecting

Dr. Philpott proceeded into a discussion of the second topic reviewed at the January 2012 meeting, which assessed exposure during the application of a pesticide product using an aerosol can. He identified an instance in the draft report where Ms. Sherman had indicated that the Board erroneously suggested that the participants wore a variety of clothing, while in reality all subjects wore long pants and long-sleeved shirts. The clothing was analyzed in pieces to allow the Agency to estimate the expected dermal exposure of people wearing other clothing combinations (e.g., shorts and short-sleeved shirts). Dr. Philpott stated that he had corrected the final report to reflect this.

Dr. Philpott read the science charges to the Board, which begin on line 597 of the draft report: "Was the research reported in the AEATF completed aerosol study report faithful to the design and objectives of the protocol and governing documents of the AEATF?" and "Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure of professional janitorial workers who apply liquid antimicrobial pesticide products to indoor surfaces using pressurized aerosol cans?" The Board concluded that the research reported in the completed monograph, associated field study reports and associated supplemental documents was indeed conducted in a manner

that was reasonably faithful to the design and objectives of the protocol and governing documents of the AEATF. The Board also concluded that the Agency has adequately, but not completely, considered the limitations in this study when using the data in estimating the dermal and inhalation exposure of those who apply liquid antimicrobial pesticide products for indoor surface disinfecting using a pressurized aerosol can. In particular, the Board noted several issues, limitations and concerns with the data and analyses.

Dr. Philpott indicated that there was one significant issue for consideration by the Board. Ms. Sherman had pointed out that on line 702 of the draft report, the Board recommended the use of 10 micrometer (µm) or smaller (< 10 µm) size results from the RespiCon™ Particle Sampler because this size range represents the fraction that enters the respiratory tract and provides a more conservative estimate of inhalation exposure. EPA, however, considers 100 µm or smaller (< 100 µm) to be a better particle cut-off size for a variety of reasons. The Board members need to consider whether they adequately characterized and provided an appropriate recommendation to the Agency given the Agency's needs. As noted by Ms. Sherman, pesticides need not be respirable to pose a hazard. Inhalation itself is a concern because particles can be absorbed through the nasal mucosa. EPA believes that the larger particle size provides a more conservative risk estimate than focusing on particles small enough to reach the lung alveoli. Dr. Popendorf questioned whether Dr. Philpott was contemplating changing the recommendation. Dr. Philpott stated that was not necessarily the case. Rather, he stated that the Board needs to consider how to address the Agency's concern that they noted in response to the draft report and suggested that they compose language to this effect for inclusion in the final report. Dr. Popendorf asserted that he was comfortable with using a particle size of either < 10 µm or < 100 µm, as there were strong arguments for both values. Dr. Popendorf suggested modifying the draft report to accommodate EPA's concerns,.

Dr. Rebecca Parkin acknowledged the valuable point raised by Ms. Sherman had not been discussed by the Board. From a public health standpoint, Dr. Parkin was comfortable recommending use of the < 100 µm particle size. Dr. Philpott suggested changing the final report to reflect that the HSRB had recommended using the < 10 µm fraction that enters the lower respiratory tract because the Board believed that this would provide a more conservative estimate of exposure, but to address the Agency's concern he would use the comments provided by Ms. Sherman to draft two to three sentences acknowledging that the < 100 µm particle size also is acceptable to use to calculate the pesticide dose via inhalation because it reflects exposure to the lower and upper respiratory tract. Dr. Popendorf agreed that was a reasonable action, and no Board members opposed the change.

However, Dr. Popendorf expressed some concerned that monitoring < 100 µm particle size does not reflect true exposure because of entry loss of large particles to the nose and mouth. Using < 100 µm might overestimate the dose entering the upper respiratory tract. Dr. Parkin agreed with Dr. Popendorf, but noted that she was not a respiratory expert and would defer to Dr. Lebowitz if he joined the call. Dr. Philpott suggested adding Dr. Popendorf's comment that "entry loss of large particles that do not enter the respiratory tract are captured by the RespiCon™ Particle Sampler and thus may lead to overestimation of exposure" after the modified text that recognizes the Agency's concern and Board recommendations. Dr. Popendorf agreed, noting that the RespiCon™ Particle Sampler is designed to collect large particles and is

more efficient than the nose; entry loss results in a loss of approximately 50 percent of the 50 µm particles, as they do not follow the air through the nose and into the lungs. Dr. Philpott stated that he will share the newly prepared paragraph with Drs. Lebowitz, Parkin and Popendorf to ensure that the language adequately reflects the Board's concerns. That proposal was acceptable to the Board members, and no additional members requested to be involved in the offline conversation regarding the revised paragraph.

Drs. Popendorf and Linda Young noted that a few sentences required more clarity in the last paragraph, which started on line 706 of the draft report: "The Board suggested that the dermal and inhalation exposure data be combined to obtain total exposure results. The Board also questioned whether a slope of 1.5, with a confidence interval (CI) including one (1), should be considered as evidence of proportionality. Furthermore, a CI that does not include one may not provide adequate protection. The Board thus recommended that the Agency always clarify coefficients over one. Finally, the Board recommended that the Agency and the Task Force refrain from using the word 'proportional' without preceding it by an adjective such as 1:1 proportional or 1:2 proportional."

Dr. Popendorf did not understand the intent of the two sentences that read, "Furthermore, a CI that does not include one may not provide adequate protection. The Board thus recommended that the Agency always clarify coefficients over one." Dr. Young explained that the concern is that a slope over one, even if the CI includes one, would not be a conservative approach with respect to human health. She suggested clarifying the language to read: "Furthermore, a CI with both limits above one would indicate that the assumption of 1:1 proportionality is not valid." In response to a question of whether the lower confidence limit would need to be more than one, Dr. Young clarified that if the point estimate was more than one, it is questionable as to whether it should be assumed to be one. Assuming a slope of one if the CI is below one is protective of human health because it indicates the upper level of what human exposure would be. However, if the point estimate is 1.5 and it is assumed to be one, the exposure evaluation is less conservative. Dr. Popendorf noted that he is not concerned about whether the point estimate is one, greater than one or less than one, but rather the exact value of the point estimate, which is captured in the last sentence of that paragraph. He emphasized that it is important for the Agency to define what is meant by "proportionality" (e.g., 1:1, 1:2 and so forth).

Dr. Popendorf suggested removing the sentence "Furthermore, a CI that does not include one may not provide adequate protection," and Dr. Young concurred, explaining that CIs are not used to provide adequate protection; they are used to estimate human exposure. The sentence was deleted, and the previous sentence was modified to read "…evidence of 1:1 proportionality." Dr. Young also addressed the sentence that reads, "The Board thus recommended that the Agency always clarify coefficients over one." She suggested that the wording be changed to reflect that the Agency needs to address, not clarify, how coefficients greater than one will be handled. The sentence was changed to read, "The Board thus recommended that the Agency always address how estimates of coefficients over one will be used." The Board members agreed that their concern was expressed adequately and noted appreciation for being able to see the changes to the document tracked in real time through the webinar.

Before proceeding, the Board members considered whether anything substantive had been lost by removing the sentence and discussed its intended meaning. Dr. Popendorf noted that if the CI is within one then there is no need for an explanation by the Agency, but beyond or below a certain range is inaccurate and requires analysis in all future reports. Dr. Young agreed, adding that if the point estimate is above one, even if the CI covers one, assuming 1:1 proportionality is inadequate because the CIs are wide. Dr. Popendorf declared that if the CI is tight and includes one (e.g., 0.9 to 1.1), he would be comfortable claiming 1:1 proportionality, but he would not have confidence in knowing where the true value lies if the CIs are wider (e.g., 0.6 to 1.8). In this scenario, there was a point estimate of 1.5 with a CI that included one, and Dr. Young was not comfortable assuming 1:1 proportionality because that would result in a less conservative estimate of exposure. Dr. Popendorf agreed that it was a valid concern and approved the modified language in the report, noting that the Board might need to clarify the issue in the future.

Dr. Philpott reminded the Board members that rather than capturing every nuance of the discussion, the final meeting report is meant to provide a condensed rationale of the HSRB's recommendations. Meeting minutes from this teleconference/webinar and the January 26, 2012 meeting will be publically available, and the Agency uses the minutes to consider carefully how to address the Board's recommendations. Dr. Philpott questioned whether Drs. Popendorf, Young and Johnson were satisfied that the substantive nature of their concern has been captured and expressed to the Agency, to which they replied affirmatively.

There being no further comments on the detailed recommendation and rationale with respect to the science charge questions, Dr. Philpott read the ethics charge question to the Board, starting on line 718, which asked whether the available information supports a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR part 26. The HSRB recommendation indicated that the Board concurred with the Agency's assessment (Sherman 2012) that the study submitted for review was conducted in substantial compliance with subparts K and L of 40 CFR part 26. Dr. Philpott asked whether any Board members had concerns, questions or comments regarding the substantive content of the detailed rationale.

Dr. Popendorf brought forth the ethics concern voiced by his colleagues at the January 2012 meeting regarding the intervention of one subject's application of pesticide during the study. He noted that this concern had been addressed by the Board from a scientific but not ethical standpoint in the report. Dr. Popendorf summarized the nature of the intervention, explaining that one applicator, who applyed more than the usual amount of the disinfectant during the cleaning process, was instructed by the director of the research study to "lighten up." The participant proceeded to use less product. Not finding instructions within the protocols to prohibit interference with application, Dr. Popendorf concluded that no provisions were explicitly violated. However, Dr. Popendorf wondered if the spirit of not interveningwas violated, and asked for some discussion from his colleagues. Dr. Jerry Menikoff rephrased Dr. Popendorf's concern, asking whether the issue was that the intervention raised ethical concerns. Dr. Menikoff noted that the subject benefitted by reduced exposure to the pesticide product. Dr. Menikoff asked whether Dr. Popendorf's concern was that had there been instructions prohibiting intervention, would it still be acceptable from an ethics standpoint. Following up on an earlier Board discussion, Dr. Menikoff indicated that the Board members had concluded that

interventions would be satisfactory within reasonable limits. If the subject was doing something to put him or her at risk for exposure, an intervention should occur, but there need not be interventions for minor deviations. The study should collect data that represent the reasonable behavior of people; sometimes people add too much product. He thought that making that clarification in future protocols would not create an ethical problem. Dr. Menikoff noted that the recommendation had been made in the science section of the draft report, which should be sufficient. Dr. Philpott reiterated that the issue fit with the substantive nature of the Board's comments particularly because the individual was not applying product in a way that was in violation of the product labeling, so there was no ethical obligation to intervene. Had the subject been engaged in behaviors that deviated from the labeling instructions and put him or her at risk of increased exposure, there might be an obligation to intervene. In this case, there was no ethical issue. Dr. Popendorf was satisfied with that explanation.

Before finalizing the draft report, Dr. Philpott will replace all instances of "incidental" with "unanticipated" and draft an additional paragraph in collaboration with Drs. Popendorf, Parkin and Lebowitz to incorporate into the document to address the Agency's concern of recommending the use of < 10 µm particle size limit as a conservative limit. The text will note EPA's concerns while articulating Dr. Popendorf's observation that using a < 100 µm particle size might overestimate exposure due to inhalation loss. Dr. Philpott solicited any remaining comments on the detailed rationale and recommendations contained within the draft final report.

There being no additional concerns, Dr. Philpott called for approval of the draft final report as amended during the teleconference/webinar meeting. All members present on the call approved the report aside from Dr. José Manautou, who was not present at the January 26, 2012, meeting and thus abstained, and Dr. Virginia Ashby Sharpe, who was no longer on the call.

SUMMARY AND NEXT STEPS

Mr. Downing thanked the Board members for a successful meeting and for their diligent work. He looks forward to receiving the final version of the Board's report with modified text summarizing the decisions made at the January 2012 meeting. He noted that the April 2012 HSRB meeting has been cancelled, and the next face-to-face HSRB meeting is scheduled to be held June 26 to 29, 2012. If the June meeting also is cancelled, the next meeting will occur during the week of October 29, 2012. Noting that the October meeting would take place after the conclusion of the terms of Drs. Philpott, Chambers, Menikoff and Lebowitz, Mr. Downing took the opportunity to acknowledge the service of these four original HSRB members. The Agency is grateful for their service on the FACA committee, which started in March 2006. Their steady guidance of the Board and dutiful service always will be remembered and appreciated.

ADJOURNMENT

Dr. Philpott thanked the Board members for their participation. The teleconference/ webinar meeting was adjourned by the Chair at 3:18 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/webinar 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: 3/27/2006–8/31/2012
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Members

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*Bernard A. Schwetz, D.V.M., Ph.D. — Term: 11/14/2011–8/31/2014
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Virginia Ashby Sharpe, Ph.D. — Term: 5/1/2010–8/31/2013
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*^Linda J. Young, Ph.D. — Term: 3/28/2008–8/31/2012
Professor and Associate Chair
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University of Florida
Gainesville, FL

*Special Government Employee (SGE)
^ Present via telephone March 28, 2012

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[Federal Register Volume 77, Number 50 (Wednesday, March 14, 2012)]
[Notices]
[Pages 15099-15101]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2012-6202]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2012-0175; FRL-9647-2]

Human Studies Review Board (HSRB); Notification of a Public Webinar/Teleconference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U. S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a public Webinar/teleconference of the HSRB to discuss its draft report from the HSRB meeting held January 26, 2012.

DATES: The Webinar/teleconference will be held on Wednesday, March 28, 2012,

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from approximately 2 p.m. to approximately 4 p.m. Eastern Time. Comments may be submitted on or before Wednesday, March 21, 2012.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2012-0175, by one of the following methods:

Internet: http://www.regulations.gov: Follow the website instructions for submitting comments.

Email: ORD.Docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center (EPA/DC), ORD Docket, Mail Code 28221T, 1200 Pennsylvania Avenue 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 online at http://www.epa.gov/epahome/dockets.htm.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2012-0175. The Agency'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 email. The http://www.regulations.gov website is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through http://www.regulations.gov, your email 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the 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 about this Webinar/teleconference should contact Jim Downing at telephone number: (202) 564-2468; fax: (202) 564-2070; email address: downing.jim@epa.gov or Lu-Ann Kleibacker at telephone number: (202) 564-7189; fax: (202) 564-2070; email address: kleibacker.lu-ann@epa.gov; mailing address: Environmental Protection Agency, Office of the Science Advisor, 8105R, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information concerning the HSRB can be found on the EPA website at http://www.epa.gov/osa/hsrb.

SUPPLEMENTARY INFORMATION:

Location: The meeting will take place via the Internet and telephone only. Access information can be found on the HSRB website: http://www.epa.gov/osa/hsrb or by contacting the persons listed under the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

Meeting access: For detailed information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least 10 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 the 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 EPA 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?

You may use http://www.regulations.gov, or you may access this **Federal Register** document via the EPA's Internet site 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 at 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; its 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 email the ORD Docket at ord.docket@epa.gov for instructions. Updates regarding the Public Reading Room access are available at 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 used that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by the 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.

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D. How may I participate in this meeting?

You may participate by providing comments in this meeting by following the instructions in this section. To ensure proper receipt by the EPA, it is imperative that you identify Docket ID No. EPA-HQ-ORD-2012-0175 in the subject line on the first page of your request.

1. *Oral comments*. Requests to present oral comments will be accepted up to and including Wednesday, March 21, 2012. 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 during the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via email) to Jim Downing or Lu-Ann Kleibacker under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Wednesday, March 21, 2012, 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*. Please 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, Wednesday, March 21, 2012. 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 EPA 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 Section 9. The HSRB provides advice, information and recommendations to the 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 the EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the EPA Science Advisor.

1. *Topics for Discussion*. The HSRB will be reviewing its draft report from the January 26, 2012 HSRB meeting. The HSRB may also discuss planning for future HSRB meetings. Background on the January 26, 2012 HSRB meeting can be found at the HSRB website: http://www.epa.gov/osa/hsrb. The January 26, 2012 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 http://www.regulations.gov and the HSRB website at http://www.epa.gov/osa/hsrb. For questions on document availability or if you do not have Internet access, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

2. *Meeting minutes and reports.* Minutes of the meeting, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters, will be releatsed within 90 calendar days of the meeting. Such minutes will be available at http://www.epa.gov/osa/hsrb and http://www.regulations.gov. In addition, information regarding the HSRB final meeting report will be found at http://www.epa.gov/osa/hsrb or from the persons listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: March 7, 2012.
Lek Kadeli,
Acting Assistant Administrator.
[FR Doc. 2012-6202 Filed 3-13-12; 8:45 am]
BILLING CODE 6560-50-P

Attachment C

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

Wednesday, March 28, 2012
2:00 p.m. - 4:00 p.m. (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE DRAFT JANUARY 26, 2012 HSRB MEETING FINAL REPORT

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA–HQ–ORD–2012–0175

2:00 PM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer [DFO], HSRB, Office of the Science Advisor [OSA], EPA)
2:10 PM*	**Meeting Administrative Procedures** – Jim Downing, DFO
2:15 PM	**Meeting Process –** Sean Philpott, Ph.D. (HSRB Chair)
2:20 PM	**Public Comments**
2:30 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, 2012 meeting.

A new scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) describing proposed research to measure dermal and inhalation exposure to workers who mix, load, and apply liquid pesticides with powered handgun equipment

Charge to the Board - Science

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of workers mixing, loading, and applying pesticides in managed horticultural facilities using powered handgun equipment?

Charge to the Board - Ethics:

- If the AHETF proposal is revised as suggested in EPA's review and if the research is performed as described, is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

A completed scenario monograph and study report from the Antimicrobial Exposure Assessment Task Force II (AEATF) in which the dermal and inhalation exposure of professional janitorial workers was monitored as they applied a liquid antimicrobial pesticide product for indoor surface disinfecting using a pressurized aerosol can

Charge to the Board:

- Was the research reported in the Antimicrobial Exposure Assessment Task Force II (AEATF) completed aerosol study report faithful to the design and objectives of the protocol and governing documents of AEATF?
- Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure of professional janitorial workers who apply liquid antimicrobial pesticide products to indoor surfaces using pressurized aerosol cans?

Charge to the Board - Ethics:

- Does available information support a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

3:55 PM* **Summary and Next Steps –** Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (DFO)

4:00 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.