Draft Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
August 25, 2016, Public Meeting
HSRB Website: www.epa.gov/osa/human-studies-review-board

Committee Members:	(See EPA HSRB Members List—Attachment A)	
Date and Time:	Thursday, August 25, 2016, 2:00–3:30 p.m. EDT (See *Federal Register* Notice—Attachment B)	
Location:	Via Teleconference and Webinar	
Purpose:	The EPA HSRB provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Liza Dawson, Ph.D.
	Vice Chair:	Edward Gbur, Jr., Ph.D.
	Board Members:	Gary L. Chadwick, Pharm.D, M.P.H, C.I.P. Kyle L. Galbraith, Ph.D. Randy Maddalena, Ph.D. Kenneth Ramos, M.D., Ph.D., Pharm.B. Suzanne M. Rivera, Ph.D., M.S.W. Jun Zhu, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and timing as presented in the Meeting Agenda (see Attachment C), unless noted otherwise.	

Introduction of Board Members and Convening of the Public Meeting

Mr. Jim Downing, Designated Federal Officer (DFO), HSRB (or Board), Office of the Science Advisor, EPA (or Agency), convened the meeting at 1:00 p.m. and welcomed Board members, EPA colleagues and members of the public. Mr. Downing conducted a roll call of the Board members, then asked the members to introduce themselves, providing their names, affiliations and areas of expertise.

Mr. Downing expressed the Agency's appreciation to the Board members for their time and efforts preparing for the meeting, and for their deliberations in developing the final report. In this meeting, the Board reviewed and discussed the final report from the July 12–13, 2016 meeting.

Mr. Downing noted that in his role as DFO under the Federal Advisory Committee Act (FACA), he serves as liaison between the HSRB and EPA and is responsible for ensuring that all FACA provisions are met regarding the operations of the HSRB. Also in his role as DFO, one of his critical responsibilities is to work with appropriate Agency officials to ensure that all appropriate ethics regulations are satisfied. HSRB members were briefed on provisions of the federal ethics and conflict-of-interest laws and have completed government financial disclosure reports, which have been reviewed to ensure that all ethics requirements are satisfied.

Mr. Downing informed Board members that they would review the final report from the July 2016 meeting and finalize the report for submission to the Science Advisor and to the Agency. He noted that agenda times are approximate and that adequate time will be allowed for Agency presentations,

public comments and the Board's deliberations. Mr. Downing told the audience that the public would be allowed to comment at the appropriate time, and that public comments would be limited to 5 minutes. He noted that no individuals had pre-registered to provide public comment.

In accordance with FACA requirements, meeting minutes, including a description of the matters discussed and decisions reached by the Board, will be prepared and must be certified by the meeting Chair within 90 calendar days. The approved minutes will be available on the HSRB website.

Virtual Meeting Operations

Because this meeting was conducted as a teleconference, Mr. Downing reminded participants to keep their telephones on mute when not speaking and, when speaking, to unmute their phones and identify themselves by name. The final report, he added, would be displayed via the Web conferencing site as the Board worked through the document. Mr. Downing turned the meeting over to Dr. Liza Dawson, HSRB Chair, who described the process for discussing the final report and reviewed guidelines for participation in the virtual meeting. She asked members to use the hand-raising feature to request the floor to speak and the approval/disapproval feature for voting.

Board Discussion of the Report

Dr. Dawson reiterated the main agenda of the meeting: to discuss the report from the July meeting and to make any changes or refinements that might be needed for the report to accurately reflect the Board's conclusions. Dr. Dawson emphasized the importance of reaching a final decision on the report at this meeting. To facilitate this schedule, minor editorial changes could be deferred until after the meeting, if necessary. She reminded the committee that both the report and the written comments submitted by Board members would be accessible during the meeting.

General Issues

Dr. Dawson called the Board's attention to the written comments, which she had grouped by thematic and logical connections. She then noted the revised wording in the report of the Board responses to the two scientific charge questions. Rather than listing the specific caveats about data limitations in the responses themselves, the responses in both studies state that the Board responded affirmatively to the charge questions, but recognized some limitations in the data, as described in the report. The Board unanimously agreed to this approach.

Study 1. Response to the EPA Science Charge (Agricultural Handler Exposure to Wettable Powders)

In reviewing the text of the detailed recommendations and rationale, Dr. Dawson explained that she attempted to capture in her revisions Dr. Randy Maddalena's comments about the data limitations, including such topics as the limitations of the kind of data that could be collected, the limited diversity of scenarios that could be tested, the difficulties in measuring inhalation exposure, and the logistical impossibility of selecting the limited number of available monitoring units randomly. The Board recognized that the researchers had done the best they could to collect data under challenging circumstances. Discussing the statistical section of the scientific recommendation, Dr. Dawson stated that she had incorporated Dr. Ed Gbur's comments, with only minor changes. Drs. Maddalena and Gbur expressed their satisfaction with the revisions. Dr. Dawson noted that she also planned to add to the final text a few references that had been recommended by Drs. Maddalena and Gbur.

Study 1. Response to the EPA Ethics Charge (Agricultural Handler Exposure to Wettable Powders)

Dr. Dawson stated that she incorporated the text submitted by Dr. Gary Chadwick verbatim into this section of the report. The Board found that review acceptable.

Study 2. Response to the EPA Science Charge (Agricultural Handler Exposure to Water Soluble Packets)

In reviewing the details of the recommendations and rationale, Dr. Dawson noted that the relatively short length of the scientific recommendation reflected both the Board's own succinct discussion in July and the fact that the data limitations in Study 2 had many similarities to those identified in Study 1. She noted that the statistics portion of the recommendation incorporates the text of Dr. Jun Zhu's statistical comments almost verbatim, with only minor editorial changes. Dr. Dawson also observed that Dr. Zhu's statistical assessment was similar to that presented in Study 1, albeit expressed somewhat differently than Dr. Gbur's analysis of Study 1.

Dr. Dawson asked for confirmation of the statistical criteria that were and were not met in this study with regard to dermal exposure and inhalation exposure. Dr. Gbur replied that the conclusions in this study were fairly straightforward; only the analysis in Study 1 engendered significant debate. Dr. Dawson planned to double-check the record to ensure that the concluding paragraph is correct.

Study 2. Response to the EPA Ethics Charge (Agricultural Handler Exposure to Water Soluble Packets)

Dr. Dawson thanked Dr. Kyle Galbraith for his text, which she used verbatim. The Board concurred on this section with no comments.

Additional Issues for Consideration

Dr. Dawson then brought up two additional issues that were not directly related to the report itself, but were nevertheless relevant to the larger question of the exposure of agricultural workers to pesticide residues. She noted that Maureen Lydon has written in detail about agricultural workers' need for additional education about proper use of pesticide products and adherence to the instructions on the label. Although educational issues lie outside the purview of topics with which the Board is charged, she nevertheless thought it appropriate to bring that message to the Board. Certainly, any increased understanding of agricultural handler exposure to pesticides that emerges from this research would be a welcome outcome for agricultural workers.

Dr. Dawson also was struck by the differences in agricultural worker exposure to pesticides seen in Study 1 and Study 2. The results of these studies suggest that wettable powders result in much greater pesticide exposure than do water-soluble packets. She recognized that the whole point of developing the packets was explicitly to reduce the kinds of exposure seen with wettable powders. Acknowledging that this kind of observation was inappropriate to include in the report, Dr. Dawson commented that educational outreach about these differences might be warranted. Regardless of the scientific challenges and despite the difficulties in collecting a statistically robust set of data, the studies do provide useful information for protecting agricultural workers and the environment.

Dr. Maddelena agreed that the work presents a wonderful opportunity to gain unexpected information about worker exposures and that it is appropriate to reduce those exposures whenever possible.

Public Comments

Mr. Downing indicated that no requests to provide public comments had been received by EPA in advance of the meeting. Dr. Dawson then called for comments from members of the public participating via teleconference. Hearing no response, Dr. Dawson proceeded to the next item on the agenda: formal approval of the final report.

Approval of the Final Report

Dr. Dawson called for final approval of the report, pending minor editorial corrections and incorporation of additional references in the scientific recommendations for Study 1. The Board approved the report unanimously.

Mr. Downing said that the report would be finalized soon and posted on the HSRB website. The report also would be transmitted to the EPA Science Advisor and to the Office of Pesticide Programs.

Adjournment

Mr. Downing announced that the next HSRB meeting is scheduled for October 18–20, 2016. An additional day, October 18, was added because several items need to be included on the agenda. Although he was not sure how many of these days, or which of these days, would actually be used for the meeting, he asked Board members to hold those dates until the agenda is finalized. He also asked Board members to notify him of any scheduling conflicts with a potential meeting on October 18. Notification of the final schedule will be posted on the HSRB website[1] and published in the *Federal Register*.

Mr. Downing and Dr. Dawson recognized departing Board member Dr. Kenneth Ramos and thanked him for his service to the Board. Dr. Ramos, in turn, thanked his colleagues for the opportunity to participate in the work of the Board. Mr. Downing announced that Dr. Helen Suh also would be departing the Board after this meeting.

Mr. Downing thanked the Board members once again for their contributions to the final report, and adjourned the meeting at 3:30 p.m. EDT.

Respectfully submitted:

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

[1] The HSRB website is available at www.epa.gov/osa/human-studies-review-board.

Certified to be true by:

Liza Dawson, Ph.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public 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.

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

Liza Dawson, Ph.D.
Research Ethics Team Leader
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Vice Chair

Edward Gbur, Jr., Ph.D.
Professor of Statistics
Director, Agricultural Statistics Laboratory
University of Arkansas
Fayetteville, AR

Members

Gary L. Chadwick, Pharm.D., M.P.H., C.I.P.
Senior Consultant
HRP Consulting Group, Inc.
Fairport, NY

George C. J. Fernandez, Ph.D.
Statistical Training Specialist
SAS Institute
Sparks, NV

Kyle L. Galbraith, Ph.D.
Research Integrity Officer
University of Illinois at Urbana-Champaign
Office of the Vice Chancellor for Research
Champaign, IL

Jewell H. Halanych, M.D., M.Sc.
Assistant Professor
Internal Medicine Residency Program
Montgomery Regional Campus
The University of Alabama at Birmingham
Birmingham, AL

Members (continued)

Randy Maddalena, Ph.D.
Physical Research Scientist
Indoor Environment Group
Lawrence Berkeley National Laboratory
Berkeley, CA

Kenneth Ramos, M.D., Ph.D., Pharm.B.
Associate Vice President
Precision Health Sciences
Professor of Medicine
Arizona Health Sciences Center
Tucson, AZ

Suzanne M. Rivera, Ph.D., M.S.W.
Vice President for Research and Technology Management
Case Western Reserve University
Cleveland, OH

Helen H. Suh, Ph.D.
Associate Professor of Health Sciences
Northeastern University
Boston, MA

Jun Zhu, Ph.D.
Professor of Statistics and of Entomology
Department of Statistics
University of Wisconsin–Madison
Madison, WI

Consultant to the Board:

Kendra L. Lawrence, Ph.D., BCE, PMP
Health Sciences Product Manager
U.S. Army Medical Materiel Development Activity
Silver Spring, MD