

US EPA ARCHIVE DOCUMENT

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
OCTOBER 2010 PUBLIC MEETING

Environmental Protection Agency Conference Center
Lobby Level - One Potomac Yard (South Bldg.)
2777 S. Crystal Drive, Arlington, VA 22202

October 27, 2010

- 10:30 AM*** Convene Public Meeting and Review Administrative Procedures – Jim Downing (Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor)
- 10:35 AM** Introduction and Identification of Board Members – Sean Philpott, Ph.D. (HSRB Chair)
- 10:40 AM** Welcome – Dr. Paul Anastas, Science Advisor (Office of the Science Advisor)
- 10:45 AM** EPA Follow-up on Previous HSRB Recommendations – Mr. William Jordan (OPP, EPA)
- Session 1:** Carroll-Loye Biological Research, Inc. Protocol *No Mas 003*, a Field Efficacy Test of PMD and Lemongrass Oil-based Repellent “No Mas” Against Mosquitoes
- 10:55 AM** EPA Science and Ethics Reviews – Dr. Clara Fuentes (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
- 11:25 AM** Board Questions of Clarification – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
- 11:55 PM** Public Comments
- 12:10 PM** Board Discussion

Charge to the Board:

If the proposed field repellency study protocol No Mas 003 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 efficacy of the tested material in repelling mosquitoes?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

12:50 PM Lunch

*Agenda times are approximate and subject to change. 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

Session 2: A new scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) to measure dermal and inhalation exposure to applicators who use backpack sprayers or hand gun sprayers to apply pesticides in utility rights-of-way

- 2:00 PM EPA Science and Ethics Reviews** – Mr. Jeff Evans (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
- 2:45 PM Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
- 3:15 PM Public Comments**
- 3:30 PM Board Discussion**

Charge to the Board:

If the proposed Agricultural Handler Exposure Task Force (AHETF) Right-of-Way application scenario and field study protocol AHE400 is revised as suggested in EPA's review and if it is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of workers who apply pesticides in utility rights-of-way with backpack or hand gun sprayers?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

5:00 PM Adjournment

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October 28, 2010

- 8:30 AM** **Open Meeting** – Jim Downing (Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor)
- 8:35 AM** **Introductions of Members** – Sean Philpott, Ph.D. (HSRB Chair)
- 8:40 AM** **Follow-up From Previous Day** – Mr. William Jordan (OPP, EPA)
- Session 3:** **Completed scenario monograph and study report from the Antimicrobial Exposure Assessment Task Force II (AEATF–II): Dermal and Inhalation Exposure of Professional Janitorial Workers Applying Liquid Antimicrobial Products to Indoor Floors Using Bucket and Mop**
- 8:45 AM** **EPA Science and Ethics Reviews** –Mr. Tim Leighton (OPP, EPA) and Mr. John Carley (OPP, EPA)
- 9:45 AM** **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
- 10:15 AM** **Public Comments**
- 10:30 AM** **Break**
- 10:45 AM** **Board Discussion**

Charge to the Board:

In the completed scenario monograph and study report AEA03 from the Antimicrobial Exposure Assessment Task Force II (AEATF–II):

- Was the research reported in the Antimicrobial Exposure Assessment Task Force II (AEATF–II) completed study report AEA03 and associated supplemental reports faithful to the design and objectives of the protocol and governing documents of AEATF-II?
- 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 antimicrobial floor-cleaning products with mop and bucket?
- Does available information support a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

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12:30 PM Lunch

Session 4: Revised scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) describing proposed research to monitor exposure of workers who mix and load pesticides formulated as wettable powders in water-soluble packaging

1:30 PM EPA Science and Ethics Reviews – Mr. Jeff Evans (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)

2:00 PM Board Questions of Clarification – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor

2:15 PM Public Comments

2:30 PM Board Discussion

Charge to the Board:

If the revised AHETF scenario and field study proposal AHE120 is revised as suggested in EPA's review, and if it is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who mix and load pesticides in water-soluble packaging?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

3:45 PM Preview of Upcoming Meetings – Ms. Kelly Sherman (OPP, EPA)

4:00 PM Adjournment

HSRB WEB SITE: <http://www.epa.gov/osa/hsrb/>

Docket Telephone: (202) 566-1752

Docket Number: EPA-HQ-ORD-2010-0797

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