

US EPA ARCHIVE DOCUMENT

4/3/08 DRAFT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
APRIL 9-10, 2008
PUBLIC MEETING

Wednesday, April 9, 2008
Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202

HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2008-0033

BOARD MEMBER ASSIGNMENTS

- **8:30 AM** Convene Meeting and Identification of Board Members – Celia Fisher, Ph.D. (HSRB Chair)
- **8:40 AM** Welcome – George Gray, Ph.D. (EPA Science Advisor)
- **8:50 AM** Opening Remarks – Debbie Edwards, Ph.D. (Director, Office of Pesticide Programs, [OPP], EPA)
- **9:00 AM** Meeting Administrative Procedures - Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)
- **9:05 AM** Update On Revisions To The EPA Document “Scientific And Ethical Approaches For Observational Exposure Studies”– Roy Fortmann, Ph.D. (Office of Research and Development, EPA)
- **9:35 AM** EPA Follow-up on Pesticide Specific HSRB Recommendations – Mr. William Jordan (OPP, EPA)

Overview of EPA’s Assessment of Proposed Pesticide Handler Research

Sampling Strategies in Proposed Pesticide Handler Research

- **9:50 AM** EPA Presentation - Mr. William Jordan (EPA, OPP)
- **10:30 AM** Break
- **10:45 AM** HSRB Workgroup Report on Sampling Strategies in Proposed Pesticide Handler Research - Celia Fisher, Ph.D. (HSRB Chair)
- **11:00 AM** Public Comments
- **11:15 AM** Board Discussion
- **11:45 AM** Lunch

Antimicrobial Exposure Assessment Task Force (AEATF) Governing Document

- **12:45 PM** **EPA Science and Ethics Assessment of Revisions to AEATF's Governing Document** – Mr. David Miller (OPP, EPA)
- **1:00 PM** **Public Comments**
- **1:15 PM** **Board Discussion**

EPA Review of AEATF-II Mop and Wipe Scenarios

- **1:45 PM** **Background, Context and Sampling Design** – Mr. John Carley, (OPP, EPA)
- **2:15 PM** **Science Assessments** - Mr. Tim Leighton (OPP, EPA) and Cassi Walls, Ph.D. (OPP, EPA)
- **3:15 PM** **Break**
- **3:30 PM** **Ethics Assessments** - Mr. John Carley (OPP, EPA)
- **4:00 PM** **Public Comments**
- **4:30 PM** **Board Discussion** (Note: due to similarities with the mop and wipe protocols, both exposure scenarios will be discussed together)

Science

If the proposed research described in AEATF's proposed mop scenario design, protocol, and supporting documentation is revised as suggested in EPA's review, does the research appear likely to generate scientifically reliable data, useful for assessing the exposure of handlers who apply an antimicrobial pesticide by mopping?

If the proposed research described in AEATF's proposed wipe scenario designs, protocol, and supporting documentation is revised as suggested in EPA's review, does the research appear likely to generate scientifically reliable data, useful for assessing the exposure of handlers who apply an antimicrobial pesticide by wiping?

- **5:45 PM** **Adjournment** - Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (HSRB DFO)

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- **8:30 AM** Convene Meeting – Celia Fisher, Ph.D. (HSRB Chair)
- **8:40 AM** Follow-up From Previous Day's Discussion – Mr. William Jordan (OPP, EPA)

EPA Review of AEATF-II Mop and Wipe Scenarios

Ethics

If the proposed research described in AEATF's proposed mop scenario design, protocol, and supporting documentation is revised as suggested in EPA's review, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

If the proposed research described in AEATF's proposed wipe scenario designs, protocol, and supporting documentation is revised as suggested in EPA's review, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

ICR Protocol: A382

- **10:00 PM** EPA Science and Ethics Assessment of ICR Protocol: A382– Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **10:45 AM** Break
- **11:00 AM** Public Comments
- **11:15 PM** Board Discussion

If the proposed research described in ICR's proposed picaridin protocol is revised as suggested in EPA's review, does the research appear likely to generate scientifically reliable data, useful for assessing the efficacy of the test substances for repelling stableflies?

If the proposed research described in ICR's proposed picaridin protocol is revised as suggested in EPA's review, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

- **12:15 PM** Lunch

Carroll-Loye Biological Research Completed Studies: SCI 001.4 and SCI 001.5

- **1:15 PM** EPA Science and Ethics Assessment of Carroll-Loye Biological Research Completed Studies: SCI 001 and SCI 002 - Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **2:00 PM** Public Comments
- **2:15 PM** Board Discussion

Are these studies sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the formulations tested against mosquitoes?

Does available information support a determination that this study was conducted in substantial compliance with subparts K and L of EPA regulations at 40 CFR part 26?

- **3:15 PM** Concluding remarks - Mr. William Jordan (OPP, EPA)
- **3:30 PM** Adjournment - Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (HSRB DFO)

* Please be advised that agenda times are approximate and subject to change. For further information, please contact the Designated Federal Officer for this meeting, Paul Lewis, via telephone: (202) 564-8381 or email: lewis.paul@epa.gov