

US EPA ARCHIVE DOCUMENT

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
APRIL 2011 PUBLIC MEETING AGENDA

Holiday Inn National Airport
2650 Jefferson Davis Highway
Arlington, VA 22202

Wednesday, April 13, 2011

- 9:00 AM*** **Convene Public Meeting and Review Administrative Procedures** – Mr. Jim Downing (Designated Federal Officer [DFO], EPA Human Studies Review Board, Office of the Science Advisor [OSA])
Introduction and Identification of Board Members – Dr. Sean Philpott (HSRB Chair)
Welcome - Dr. Warren Lux (Director of the Program in Human Research Ethics, OSA, EPA)
Opening Remarks – Steven Bradbury, Ph.D. (Director, Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention, EPA)
Office of Pesticide Programs (OPP) Follow-up on Previous HSRB Recommendations – Ms. Kelly Sherman, (OPP, EPA)

Session 1: Completed AHETF research on exposure of workers applying pesticide sprays using open-cab airblast equipment.

- 9:30 AM** **EPA Science and Ethics Reviews** – Mr. Matthew Crowley (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
10:30 AM **Board Questions of Clarification** – Dr. Sean Philpott (HSRB Chair)
11:00 AM **Public Comments**
11:15 AM **Break**
11:30 AM **Board Discussion - Science**

Charge to the Board:

Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph report and associated field study reports faithful to the design and objectives of the protocol, SOPs, and governing documents?
Has EPA 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 pesticides with open cab airblast equipment?

12:15 PM **Board Discussion - Ethics**

Charge to the Board:

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

* 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

12:45 PM Lunch

Session 2: A published report (Gulson et al. 2010) of an intentional exposure human study measuring dermal absorption of zinc oxides contained in sunscreens.

1:30 PM EPA Science and Ethics Reviews – Dr. Jessica Ryman (OPP, EPA) and Ms. Laura Parsons (OPP, EPA)

2:15 PM Board Questions of Clarification – Dr. Sean Philpott (HSRB Chair)

2:45 PM Public Comments

3:00 PM Board Discussion - Science

Charge to the Board:

Is the Gulson et al. (2010) study scientifically sound, providing reliable data?
If so, is the Gulson et al. (2010) study relevant for qualitative use in support of an assessment of the absorption of zinc oxide through the skin?

3:45 PM Break

4:00 PM Board Discussion - Ethics

Charge to the Board:

Is there adequate information to determine that the Gulson et al. (2010) study was conducted in substantial compliance with procedures at least as protective as those in subparts A - L of EPA's regulation at 40 CFR Part 26?

Session 3: Reconsideration of two concerns previously raised by the HSRB in its June 2009 review of an intentional human dosing study with chlorpyrifos (Kisicki et al., 1999); additional pertinent information was made available by the sponsor related to these two concerns.

4:30 PM Introduction of Topic - Dr. Sean Philpott (HSRB Chair)

4:45 PM Board Discussion – Science

Issues for Discussion:

Do the recommendations provided by the HSRB at its June 2009 meeting and in its subsequent report regarding the reliability of data on the urinary metabolite trichloropyridinol in the Kisicki et al. (1999) study change in light of the new information provided?

Do the recommendations provided by the HSRB at its June 2009 meeting and in its subsequent report regarding the level of absorption of chlorpyrifos in the Kisicki et al. (1999) study change in light of the new information provided?

5:30 PM Adjournment

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Thursday, April 14, 2011

10:00 AM* **Convene Public Meeting** – Mr. Jim Downing (DFO, HSRB, OSA)
Introduction and Identification of Members – Dr. Sean Philpott (HSRB Chair)
Follow-up from Previous Day - Ms. Kelly Sherman, (OPP, EPA)

Session 1: Completed AEATF research on exposure of professional janitorial workers when wiping indoor surfaces with an antimicrobial pesticide.

10:15 AM EPA Science and Ethics Reviews – Mr. Timothy Leighton (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)

11:00 AM Board Questions of Clarification – Dr. Sean Philpott (HSRB Chair), EPA, Principal Investigator/Sponsor

11:30 AM Public Comments

11:45 AM Board Discussion - Science

Charge to the Board:

Was the research reported in the Antimicrobial Exposure Assessment Task Force II (AEATF) completed wipe 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 exposure of those who clean indoor surfaces with antimicrobial pesticides using a trigger-bottle and wipes or ready-wipes?

12:30 PM Board Discussion - Ethics

Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

1:00 PM Preview of Upcoming Meetings – Ms. Kelly Sherman (OPP, EPA)

1:10 PM Adjournment

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