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US ENVIRONMENTAL PROTECTION AGENCY HUMAN STUDIES REVIEW BOARD JANUARY 2011 PUBLIC MEETING

Environmental Protection Agency Conference Center

Lobby Level - One Potomac Yard (South Bldg.) 2777 S. Crystal Drive, Arlington, VA 22202

January 26, 2011

9:15 AM*	Convene Public Meeting and Review Administrative Procedures – Jim
	Downing (Designated Federal Officer, EPA Human Studies Review Board,
	Office of the Science Advisor)
9:20 AM	Opening Remarks - Dr. Warren Lux, Director of the Program in Human
	Research Ethics (Office of the Science Advisor)
9:25 AM	Introduction and Identification of Board Members – Sean Philpott, Ph.D.
	(HSRB Chair)
9:30 AM	OPP Welcome and Follow-up on Previous HSRB Recommendations –
	Mr. William Jordan (OPP, EPA)
Session 1:	Agricultural Handler Exposure Task Force (AHETF) report of a completed scenario monograph and study reports of five field studies
	measuring the dermal and inhalation exposure of workers applying
	liquid spray pesticides to tree or trellis crops using closed cab airblast
	equipment.
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- **9:40 AM EPA Science and Ethics Reviews** Mr. Matthew Crowley (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
- **10:25 AM** Board Questions of Clarification Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
- **10:55 AM Break**
- 11:10- AM Public Comments
- 11:25 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 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 conventional pesticides with closed cab airblast equipment?

12:30 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

1:15 PM Board Discussion Continued - 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?
- Session 2: Agricultural Handler Exposure Task Force (AHETF) scenario design and associated protocol describing proposed research to monitor exposure of workers who mix and load pesticides formulated as wettable powders.
- **2:15 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 Break
- 3:45 PM Board Discussion

Charge to the Board:

If the revised AHETF scenario and field study proposal AHE80 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 handlers who perform open mixing and loading of pesticide end use products formulated as wettable powders?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

5:15 PM Adjournment

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