6/15/09 DRAFT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
JUNE 24-25, 2009
PUBLIC MEETING

JUNE 24, 2009
Holiday Inn National Airport
2605 Jefferson Davis Highway
Arlington, VA
703 684 7200

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2009-0183

- **9:30 AM** **Convene Meeting and Administrative Procedures –** Paul Lewis, Ph.D. (Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor)
- **9:40 AM** **Introduction and Identification of Board Members** – Sean Philpott, Ph.D. (HSRB Chair)
- **9:50 AM** **Welcome –** Kevin Teichman, Ph.D. (Acting Science Advisor, Office of the Science Advisor)
- **10:00 AM** **Opening Remarks –** Debbie Edwards, Ph.D. (Director, Office of Pesticide Programs, EPA)
- **10:10 AM** **EPA Follow-up on Pesticide Specific HSRB Recommendations –** Mr. William Jordan (OPP, EPA)

Chlorpyrifos Human Toxicity Studies

- **10:15 AM** **EPA Science and Ethics Reviews -** Anna Lowit, Ph.D. (OPP/EPA), John Doherty, Ph.D. (OPP/EPA), Mr. Wade Britton (OPP/EPA), and Mr. John Carley (OPP/EPA)

  Board Questions of Clarification – Sean Philpott, Ph.D. (HSRB Chair)
  EPA -
  Principle investigator/sponsor -
- **12:00 PM** **Lunch**
- **12:45 PM** **Public Comments**
- **1:00 PM** **40 CFR §26.1706** - Mr. William Jordan (OPP, EPA)
- **1:15 PM** **Review and Discussion of HSRB Approaches for Consideration of Pre-Rule Human Dosing Studies -** Sean Philpott, Ph.D. (HSRB Chair)
- **2:15 PM** **Board Discussion**

The Agency is taking a new path in its assessment of chlorpyrifos, basing the RfD on data from pregnant rats, fetuses, and post-natal rats. Since the available human studies address only cholinesterase inhibition rather than other endpoints, they are not directly relevant to the forthcoming risk assessment focused on pregnant women and children. EPA proposes to use the three human studies listed below to characterize and help interpret epidemiological and biomonitoring data, using bounding estimates as described in the White Paper and potentially using physiologically-based pharmacokinetic (PBPK) models.

1.1 Nolan *et al.* (1982)

1.1.1 Are the blood and urine measurements of chlorpyrifos and/or TCP from the Nolan *et al.* oral and dermal studies reliable and appropriate for use in characterizing the results of epidemiological studies with chlorpyrifos?

1.1.2 Are the measurements of cholinesterase activity/inhibition from the Nolan *et al.* oral and dermal studies reliable?

1.1.3 Is there clear and convincing evidence that the conduct of the Nolan *et al*. study was fundamentally unethical, or significantly deficient relative to the standards of ethical research conduct prevailing when it was conducted?

1.2 Honeycutt and DeGeare (1993)

1.2.1 Are the blood and urine measurements of chlorpyrifos and/or TCP from the Honeycutt and DeGeare worker biomonitoring study reliable and appropriate for use in characterizing results of the epidemiological studies with chlorpyrifos?

1.2.2 Are the measurements of cholinesterase activity/inhibition from the Honeycutt and DeGeare worker biomonitoring study reliable?

1.2.3 Is there clear and convincing evidence that the conduct of the Honeycutt and DeGeare study was fundamentally unethical, or significantly deficient relative to the standards of ethical research conduct prevailing when it was conducted?

1.3 Kisicki *et al.* (1999)

1.3.1 Are the blood and urine measurements of chlorpyrifos and/or TCP from the Kisicki *et al.* oral study reliable and appropriate for use in characterizing the results of epidemiological studies with chlorpyrifos?

1.3.2 Are the measurements of cholinesterase activity/inhibition from the Kisicki *et al.* oral study reliable?

1.3.3 Is there clear and convincing evidence that the conduct of the Kisicki *et al.* study was fundamentally unethical, or significantly deficient relative to the standards of ethical research conduct prevailing when it was conducted?

1.3.4 If the HSRB agrees with OPP that the conduct of the Kisicki et al. study was significantly deficient relative to the standards of ethical research prevailing when it was conducted, please provide any additional comments relative to EPA's proposal to rely on the data pursuant to 40 CFR §26.1706.

- **4:00 PM** **Break**
- **4:15 PM** **Board Summary**

Review of February 17, 2009 HSRB Meeting Report

- **4:45 PM** **Review Process -** Sean Philpott, Ph.D. (HSRB Chair)
- **4:50 PM** **Public Comment**
- **5:00 PM** **Board Discussion and Decision on Report -** Sean Philpott, Ph.D. (HSRB Chair)
- **5:45 PM** **Concluding remarks –** Mr. William Jordan (OPP, EPA)
- **5:50 PM** **Adjournment** – Sean Philpott, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (HSRB DFO)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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JUNE 25, 2009

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2605 Jefferson Davis Highway
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- **8:30 AM** **Opening of Meeting –** Paul Lewis, Ph.D. (HSRB DFO)
- **8:35 AM** **Introduction –** Sean Philpott, Ph.D. (HSRB Chair)
- **8:40 AM** **Follow-up From Previous Day –** Mr. William Jordan (OPP, EPA)

Carroll-Loye Biological Research, Inc. Protocol LNX-002: Efficacy of Picaridin-Based Personal Insect Repellents against Biting Flies in the Field

- **8:45 AM** **EPA Science and Ethics Reviews -** Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **9:30 AM** **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair)
  EPA -
  Principle investigator/sponsor -
- **9:50 AM** **Public Comments**
- **10:05 AM** **Board Discussion**

If the proposed field repellency study protocol LNX-002 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the efficacy of the tested materials in repelling biting flies in the field?

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

- **10:55 AM** **Break**
- **11:10 AM** **Board Summary**

ICR, Inc. Study A382: Efficacy of Picaridin-Based Personal Insect Repellents against Stable Flies in the Laboratory

- **11:25 AM** **EPA Science and Ethics Reviews –** Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **12:00 PM** **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair)
  EPA -
  Principle investigator/sponsor –

- **12:15 PM Lunch**
- **1:00 PM Public Comments**
- **1:15 PM Board Discussion**

1. Is the ICR study A382 sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the tested formulations against stable flies in the laboratory?

2. Does available information support a determination that study A382 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

- **2:00 PM Break**
- **2:15 PM Board Summary**

Agricultural Handlers Exposure Task Force (AHETF) Scenario Design and Field Study Protocol: Mixing /Loading Wettable Powder in Water Soluble Packaging

- **2:30 PM** **EPA Science and Ethics Reviews -** Mr. Jeff Evans (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
- **3:30 PM** **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair)
  EPA -
  Principle investigator/sponsor –
- **3:50 PM Public Comments**
- **4:05 PM Board Discussion**

If the proposed mix/load water soluble packing SP field study protocol AHE120 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who mix and load soluble or wettable powder pesticides in water-soluble packaging?

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

- **5:05 PM Board Summary**
- **5:20 PM** **Concluding remarks –** Mr. William Jordan (OPP, EPA)
- **5:25 PM** **Adjournment** – Sean Philpott, 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