



UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY  
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

December 29, 2017

**MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review Board for its  
January 23-24, 2018 Meeting

**TO:** Thomas O'Farrell  
Designated Federal Official  
Human Studies Review Board  
Office of Science Advisor

**FROM:** Michelle Arling  
Human Research Ethics Review Officer  
Office of the Director  
Office of Pesticide Programs

This memorandum identifies the materials that the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is providing for review by the Human Studies Review Board (HSRB or Board) at the teleconference and virtual meeting scheduled for January 23-24, 2018. At this meeting, EPA will ask the Board to address scientific and ethical issues surrounding two topics, and to respond to specific charge questions focused on the research identified below.

**1. AHETF Study Report (AHE170) – Open Pour Loading of Granules**

First, the Board will consider a scenario monograph report and completed study report that summarize the Agricultural Handler Exposure Task Force, LLC (AHETF)-sponsored research to monitor dermal and inhalation exposure during open pour loading of granular pesticide products. Because the research involved scripted exposure, it meets the regulatory definition of "research involving intentional exposure of a human subject" and thus is covered by subparts K and L of EPA's amended rule for the protection of human subjects of research. The rule at 40 CFR §26.1125 requires a sponsor or investigator to submit to EPA, before conducting a study involving intentional exposure of human subjects, the protocol and related materials describing the proposed human research. The HSRB reviewed the protocol and related materials on November 5, 2014. In addition, EPA's regulation at 40 CFR §26.1601 requires EPA to seek HSRB review of the completed research. The charge questions and documents being transmitted to the HSRB for

review are listed below.

### **Charge to the Board - Science:**

- Is the research presented in AHE170 and the associated documents scientifically sound, providing reliable data useful for assessing the exposure of those who perform open pour loading of granular pesticide products?

### **Charge to the Board - Ethics**

- Does the available information support a determination that the study was conducted in substantial compliance with the applicable requirements of 40 CFR part 26?

### **Documents**

- a. EPA DRAFT Review of “Determination of Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules” (AHE170)
- b. EPA DRAFT Review of Agricultural Handler Exposure Task Force (AHETF) Monograph: “Open Pour Loading of Granules” (AHE1017)
- c. EPA Field Analytical Review of Data from Agricultural Handler Exposure Task Force (AHETF) Monograph: “Open Pour Loading of Granules” (AHE1017) – Excel spreadsheet
- d. EPA Ethics Review of Completed AHETF Study AHE170 on Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules
- e. EPA Summary of files associated with AHE170
- f. AHETF AHE170 Study Report: Determination of Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules, dated October 3, 2017
- g. AHETF IRB Correspondence Report for Study AHE170, Dated September 25, 2017
- h. AHETF Agricultural Handler Exposure Scenario Monograph: Open Pour Loading of Granules (Report No. AHE1017), dated October 25, 2017
- i. AHETF Standard Operating Procedures, dated January 12, 2015
- j. AHETF Governing Document, dated August 12, 2010
- k. HSRB November 5, 2014 EPA Human Studies Review Board Meeting Report, dated January 20, 2015 (<https://www.epa.gov/sites/production/files/2015-01/documents/hsrb-5-nov-2014-final-report.pdf>)

## **2. Protocol for “Laboratory Evaluation of Bite Protection from Repellent-Impregnated Fabrics”**

Second, the Board will consider a new protocol from submitted by Landis and written by the U.S. Department of Agriculture describing proposed research to determine the bite protection level provided by knit and woven fabrics treated with permethrin or etofenprox. Because the proposed research involves scripted exposure, it meets the regulatory definition of “research involving intentional exposure of a human subject” and thus is covered by subparts K and L of EPA’s amended rule for the protection of human subjects of research. The rule at 40 CFR §26.1125 requires a sponsor or investigator to submit to EPA, before conducting a study involving intentional exposure of human subjects, the protocol and related materials describing the proposed human research. In addition, EPA’s regulation at 40 CFR §26.1601 requires EPA to perform science and ethics reviews of the submitted proposal and to seek HSRB review of the proposed research. EPA has reviewed the protocol, and has concluded that the research, with minor

revisions, is likely to generate scientifically sound, useful information and to meet the applicable provisions of the EPA regulations in 40 CFR part 26, subparts K and L. The charge questions and documents being transmitted to the HSRB for review are listed below.

**Charge to the Board - Science:**

- Is the protocol “Laboratory Evaluation of Bite Protection from Repellent-Impregnated Fabrics” likely to generate scientifically reliable data, useful for estimating the level of mosquito bite protection provided by the different textiles treated with permethrin or etofenprox?

**Charge to the Board - Ethics:**

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

**Documents**

- a. EPA’s Science and Ethics Review of Protocol for Laboratory Evaluation of Bite Protection from Insecticide-Impregnated Fabrics
- b. Protocol titled “Laboratory Evaluation of Bite Protection from Repellent-Impregnated Fabrics”, dated August 9, 2017
- c. Supplemental Materials to Address Ethical Requirements for the Protocol Entitled: Laboratory Evaluation of Bite Protection from Repellent-Impregnated Fabrics, dated November 7, 2017