



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 1, 2015

MEMORANDUM

SUBJECT: Materials for Review by the Human Studies Review Board for its
April 22-23, 2015 Meeting

TO: Jim Downing
Designated Federal Official
Human Studies Review Board
Office of Science Advisor (8105R)

FROM: Kelly Sherman
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This memorandum describes 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 meeting scheduled for April 22-23, 2015. At this meeting, EPA will ask the Board to address scientific and ethical issues surrounding two topics, each of which is discussed further below:

1. A report from the Agricultural Handler Exposure Task Force (AHETF) of completed research monitoring the exposure of workers applying pesticides to utility rights-of-way using backpack and handgun spray equipment.
2. A new protocol from S.C. Johnson & Son, Inc. describing proposed efficacy testing in the field of various S.C. Johnson skin-applied mosquito repellent products.

1. AHETF Completed Study AHE400: Exposure of Workers Applying Pesticides to Utility Rights-of-Way using Backpack and Handgun Spray Equipment:

In October 2010, the HSRB reviewed a protocol for research to measure the levels of dermal and inhalation exposure received by pesticide applicators who spray pesticides in utility rights-of-way using backpack and handgun spray equipment. Following favorable EPA and HSRB reviews of the protocol, and after revisions to address EPA and HSRB comments, this research was conducted between May 2011 and September 2013. The completed reports and monograph were submitted to EPA in October 2013. If the data for this scenario are accepted by EPA, the resulting data will be added to the Agricultural Handler Exposure Database (AHED®). EPA intends to use these data generically to estimate daily dermal and inhalation exposures of workers who treat utility rights-of-way using backpack and handgun spray equipment.

Because this 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 §26.1303 requires the submitter of reports of completed human research to document its ethical conduct. The rule at 40 CFR §26.1604 requires EPA to “review the material submitted under §26.1303 and other available, relevant information, and [to] document its conclusions regarding the scientific and ethical conduct of the research.” The rule at 40 CFR §26.1604 further requires EPA to submit the data and EPA’s review to the HSRB if it decides to rely on the data.

EPA has reviewed the AHETF completed study report, IIRB correspondence report, and monographs, and has concluded that the research provides scientifically sound, useful information, and was conducted in substantial compliance with the ethics requirements at 40 CFR part 26, subparts A through L.

Charge Questions:

1. Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph reports and associated field study report for AHE400 faithful to the design and objectives of the protocol, SOPs, and governing documents?
2. 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 liquid pesticide sprays to utilities rights-of-way using backpack or handgun spray equipment?
3. Does available information support a determination that the studies were conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

Documents for Review for AHETF Completed Study (AHE400):

Author	File or Folder Name	Description
AHETF	AHE400 Study Report 9-17-14.pdf	AHETF submission of the field and analytical results for backpack and handgun monitoring. This single report covers monitoring for both scenarios. <i>*However, each scenario has its own monograph report.</i>
	Backpack ROW Monograph 9-29-14 Final.pdf	AHETF submission of the backpack scenario utilizing backpack-specific data from “AHE400 Study Report 9-17-14.pdf”
	Handgun-ROW Monograph 9-29-14 Final.pdf	AHETF submission of the handgun scenario utilizing handgun-specific data from “AHE400 Study Report 9-17-14.pdf”
	IRB Correspondence Report for Study AHE400 - Final 9-8-14.pdf	IRB correspondence.
	AHE400 AaiH Calculations 3-18-14 Post QA.xlsx	AHETF description and analysis spreadsheet calculating how much active ingredient is handled by each worker.
	BP-ROW Data - FF Adjusted 9-5-14 Post QA - for EPA 10-14-14.xlsx	AHETF spreadsheet compilation of backpack data
	HG-ROW Data - FF Adjusted 9-5-14 Post QA - for EPA 10-14-14.xlsx	AHETF spreadsheet compilation of handgun data
	Excel workbooks (folder)	Folder containing 31 Excel files showing dosimeter results for each worker, including field fortification analysis and adjustments.
	SAS Files AHE400-BP (folder)	Folder containing 5 statistical software programming files (SAS) and 1 .csv file. Pertains to Appendices E and F of “Backpack ROW Monograph 9-29-14 Final.pdf”.
	SAS Files AHE400-HG Scenario (folder)	Folder containing 3 statistical software programming files (SAS) and 1 .csv file. Pertains to Appendices E and F of “Handgun-ROW Monograph 9-29-14 Final.pdf”.
	AHETF GD Version 2-8-12-10 with changes accepted.pdf	The AHETF’s “Governing Document” outlining, for all potential scenarios, the overarching approach to monitoring pesticide handlers. Includes sampling design and sample size estimations.

Documents for Review for AHE400 Completed Study (continued):

Author	File or Folder Name	Description
AHETF	AHETF SOP Manual 12JAN2015 EPA Version.pdf	AHETF Standard Operating Procedures (SOPs). These SOPs are a good source of information about how many aspects of the research are conducted.
	AHE400 MU Plan 6-04-10.pdf	2010 AHETF submission outlining the monitoring plan and protocol for the completed studies under current review.
EPA	49472001.DER_AHE400_BP and HG ROW_Field-Analytical Review.doc	EPA’s review of “AHE400 Study Report 9-17-14.pdf”. Currently in draft form, to be finalized following any comments from the April 2015 HSRB meeting report.
	49478601.DER_AHE1012_Backpack ROW_Monograph Review.doc	EPA’s review of “Backpack ROW Monograph 9-29-14 Final.pdf”. Currently in draft form, to be finalized following any comments from the April 2015 HSRB meeting report.
	49478602.DER_AHE1013_Handgun ROW_Monograph Review.doc	EPA’s review of “Handgun-ROW Monograph 9-29-14 Final.pdf”. Currently in draft form, to be finalized following any comments from the April 2015 HSRB meeting report.
	EPA Review_AHE1012_BP-ROW Data.xlsx	EPA spreadsheet compilation of backpack data – based on the AHETF submission “BP-ROW Data - FF Adjusted 9-5-14 Post QA - for EPA 10-14-14.xlsx”
	EPA Review_AHE1013_HG-ROW Data.xlsx	EPA spreadsheet compilation of handgun data – based on the AHETF submission “HG-ROW Data - FF Adjusted 9-5-14 Post QA - for EPA 10-14-14.xlsx”
	EPA Ethics Review of Completed Study AHE400.pdf	EPA’s review of ethics issues for completed report.
	EPA Science and Ethics Review of AHE400 ROW final 9-30-10.pdf	EPA protocol review (covering both science and ethics), prepared prior to the October 2010 HSRB meeting.
HSRB	HSRB October 2010 Meeting Minutes.pdf	Minutes of the HSRB meeting when the protocol for this study were reviewed.
	HSRB October 2010 Meeting Report.pdf	HSRB’s report for the protocol review of this study.

2. S.C. Johnson & Son, Inc. Protocol – Field Testing of S.C. Johnson Personal Mosquito Repellent Products to Support their use of the EPA Repellency Awareness Graphic:

The Board will also consider a new protocol from S.C. Johnson & Son, Inc. describing proposed research to determine the complete protection time of up to eighteen EPA-registered S.C. Johnson skin-applied repellent products in the field against wild adult mosquito populations. 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 §26.1603 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 Questions:

If the S.C. Johnson & Son, Inc. protocol is revised as suggested in EPA’s review and if the research is performed as described:

1. Is the protocol “Field Testing of S.C. Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic” likely to generate scientifically reliable data, useful for estimating the complete protection time of various EPA-registered S.C. Johnson skin-applied mosquito repellents in the field against wild adult mosquito populations?
2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents for Review:

- a. EPA Science and Ethics Review of a Protocol for Field Testing of S.C. Johnson Skin-Applied Mosquito Repellent Products (dated March 31, 2015) (39 pages)
- b. S.C. Johnson Protocol Submission (dated February 27, 2015) (676 pages)