



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

June 21, 2016

MEMORANDUM

SUBJECT: Materials for review by the HSRB for its July 2016 Meeting

TO: Jim Downing
Designated Federal Official
Human Studies Review Board
Office of Science Advisor

FROM: Richard P. Keigwin, Jr. *Richard P. Keigwin, Jr.*
Deputy Director for Programs
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This memorandum identifies the materials and charge questions which OPP is providing for review by the Human Studies Review Board (HSRB) at the meeting scheduled for July 12 - 13, 2016. At this meeting, EPA will ask the Board to address scientific and ethical issues surrounding these two topics, each of which is discussed further below:

1. A Completed Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Wettable Powders. This was submitted by the Agricultural Handlers Exposure Task Force (AHETF); and
2. A Completed Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Pesticide Products in Water Soluble Packets (also completed by AHETF).

AHETF Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Wettable Powders

The scenario monograph report on agricultural handler exposure from open pour mixing/loading of wettable powders summarizes the results of two studies: AHE39, which was initiated prior to the effective date of the rule on protecting human subjects, and study AHE80, which was initiated after the effective date of the final rule. Under 40 CFR § 26.1604, EPA is required to seek input from the HSRB for human studies covered by EPA's human studies rule that are initiated after April 7, 2006. For human studies initiated prior to April 7, 2006, EPA may, but is not required to, consult with the HSRB unless the study was conducted to identify or measure a toxic effect.

For the July 12 – 13, 2016 HSRB meeting, EPA is seeking HSRB input on whether available information supports a determination that study AHE80 was conducted in substantial compliance with subparts K and L of 40 CFR Part 26; EPA is not seeking any HSRB feedback on the AHE39 study since HSRB review is not required and EPA has concluded that the study is scientifically valid and relevant and not unethical under § 26.1704.

Brief Introductory Background on Study AHE80

Study AHE80 developed data to determine the potential dermal and inhalation exposure for workers who mix and load pesticides formulated as wettable powders. The monitored activity included opening bags of product and pouring the powder into a variety of mixing or application equipment as well as the addition of water to the tank.

The AHE80 protocol specified five monitoring units (MUs) to be conducted in each of four geographic monitoring areas (MAs) for an expected total of 20 monitoring units. The four specified monitoring areas for AHE80 were New York (MA 81), Florida (MA 82), Michigan (MA 83), and California (MA 84). A monitoring unit or MU is a single subject carrying out scenario-specific tasks under a particular set of circumstances that represent a single workday. A monitoring unit refers to a worker who is carrying out activities using a particular pesticide formulation under a specific scenario, on a particular day. Every MU provides an estimate of a single handler-day of exposure to that pesticide. A cluster is a group of monitoring units that are performed close together in terms of location and time. Under study AHE80, all sets of samples were collected; however, the AHETF included 19 in the data analysis because MU 15 was terminated after the water source malfunctioned when MU 15 was mixing/loading his first load.

Science Charge Questions:

- Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph reports and associated field study report for AHE80 faithful to the design and objectives of the protocol?
- Did the research generate scientifically reliable data, useful for assessing the exposure of individuals who mix and load conventional pesticides formulated as wettable powders?

Ethics Charge Question:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

AHETF Study and Monograph Report for Agricultural Handler Exposure during Mixing/Loading of Pesticide Products in Water Soluble Packets (also completed by AHETF)

The documents describe the implementation and results of a field study, the objective of which was to develop data to determine the potential dermal and inhalation exposure for workers who mix and load solid pesticides packaged in water soluble packets (WSPs). The monograph report for the mixing/loading of WSPs summarizes the dermal and inhalation exposure data collected through study AHE120 for the WSP mixing/loading agricultural handler scenario.

Science Charge Questions:

- Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph reports and associated field study report for AHE120 faithful to the design and objectives of the protocol?
- Did the research generate scientifically reliable data, useful for assessing the exposure of individuals who mix and load conventional pesticides formulated in water soluble packets?

Ethics Charge Question:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

The study and support materials which were mailed to the HSRB on June 16, 2016 and the science and ethics review memos (and Appendix G to study AHE120) which will be emailed to the HSRB on June 22, 2016 are listed in the attachment.

We look forward to talking with the HSRB members and obtaining their input, and thank you for your assistance.

Attachment:

Separate List of Files for HSRB for July 12-13, 2016 HSRB Meeting

Attachment to Transmittal Memo – List of Documents for HSRB for July 12-13, 2016 HSRB Meeting

EPA Note: This flash drive which the Office of the Science Advisor (OSA) mailed to the HSRB includes study and support materials for the July 12-13, 2016 HSRB meeting. EPA’s science and ethics review memos, the transmittal memo with charge questions, and Appendix G to study AHE120 were not included on this disc and will be transmitted via electronic mail to the HSRB on June 22, 2016. The material included on the flash drive is identified in the shaded cells below. **EPA is asking the HSRB to review the completed field studies and the EPA science and ethics review materials.** The other documents are provided as background reference documents and identified as such for the HSRB on this list. Please email Jim Downing (downing.jim@epa.gov), Matthew Crowley (crowley.matthew@epa.gov) and Maureen Lydon (lydon.maureen@epa.gov) if you need any other items referenced within the studies or background documents.

Submission Description	Author	File Name	Description	
Exposure Monitoring During Mixing/Loading Wettable Powders	AHETF	AHE80 Field Study Report Final 01-27-16	Field and analytical results for AHETF study AHE80 which monitored exposure during mixing/loading of wettable powders.	
		AHE80 - IRB Correspondence Report 3-23-16	IRB correspondence for study AHE80.	
		AHE1015 Monograph for Wettable Powder Mixer Loader - Final 4-7-16	AHETF submission of the mixing/loading wettable powder scenario utilizing exposure data from AHE80 and AHE39.	
			AHETF GD Version 2 - 8-12-10 with changes accepted	This is a background document that the HSRB can use as a reference if interested. The AHETF’s “Governing Document” outlining, for all potential scenarios, the overarching approach to monitoring pesticide handlers. Includes sampling design and sample size estimations.
			AHETF SOP Manual 12JAN2015 EPA Version	This is a background document that the HSRB can use as a reference if interested and includes AHETF Standard Operating Procedures (SOPs): a compilation of standard operating procedures for many aspects of the research. Specific SOPs are referenced in study-specific protocols.
			AHE80 Heat Index Records	These are AHETF’s weather records (with heat index included) from the field notebooks for study AHE80. EPA requested these records.
			49841201.DER_AHE80_ML WP Field-Analytical Review	EPA’s science review of “AHE80 Field Study Report Final 01-27-16”. Currently in draft form, to be finalized following any comments from the July 2016 HSRB meeting report.
		EPA	49893001.DER_AHE1015_ML WP Monograph Review	EPA’s science review of “AHE1015 Monograph for Wettable Powder Mixer Loader - Final 4-7-16”. Currently in draft form, to be finalized following any comments from the July 2016 HSRB meeting report.
			EPA Review Data table AHE80+AHE39	Spreadsheet compilation of exposure monitoring data from AHE80 and AHE39. Part of science background. This is part of science review.

	EPA Ethics Review of Completed Study AHE80	EPA's ethics review of completed study AHE80.
HSRB	HSRB final report_3-17-11	This is a background document that the HSRB can use as a reference if interested. It's HSRB's final meeting report that includes the protocol review of study AHE80.

Submission Description	Author	File Name	Description	
Exposure Monitoring During Mixing/Loading Water Soluble Packets	AHETF	AHE120 Final Study Report 7-21-15	Field and analytical results for AHETF study AHE120 which monitored exposure during mixing/loading of water soluble packets.	
		Appendix G to study AHE120	AHETF provided this additional information on excluded work practices as Appendix G to study AHE120. The Appendix is being emailed to the HSRB.	
		AHE120 - IIRB Correspondence Report Complete 7-31-15	IRB correspondence for study AHE120.	
		AHE120 IRB meeting minutes not included with original submission	EPA requested the meeting minutes that the IRB did not include in the original submission received by EPA.	
		AHE1014 WSP Monograph - Final - 8-28-15	AHETF submission of the mixing/loading water soluble packets scenario utilizing exposure data from AHE120.	
	AHETF GD Version 2 - 8-12-10 with changes accepted		AHETF SOP Manual 12JAN2015 EPA Version	This is a background document that the HSRB can use as a reference if interested. This is the AHETF's "Governing Document" outlining, for all potential scenarios, the overarching approach to monitoring pesticide handlers. Includes sampling design and sample size estimations.
				This is a background document that the HSRB can use as a reference if interested and includes AHETF Standard Operating Procedures (SOPs): a compilation of standard operating procedures for many aspects of the research. Specific SOPs are referenced in study-specific protocols.
		EPA	AHE120 Heat Index Records	These are AHETF's weather records (with heat index included) from the field notebooks for study AHE120. EPA requested these records.
			49680501.DER_AHE120_ML WSP Field-Analytical Review	EPA's science review of "AHE120 Final Study Report 7-21-15". Currently in draft form, to be finalized following any comments from the July 2016 HSRB meeting report.
			49411901.DER_AHE1014_ML WSP Monograph Review	EPA's science review of "AHE1014 WSP Monograph - Final - 8-28-15". Currently in draft form, to be finalized following any comments from the July 2016 HSRB meeting report.

		<p>EPA Review Data table AHE120</p> <p>EPA Ethics Review of Completed Study AHE120</p> <p>HSRB final report_12-13-10</p>	<p>Spreadsheet compilation of exposure monitoring data from AHE120. This is part of science review.</p> <p>EPA's ethics review of completed study AHE120.</p> <p>This is a background document that the HSRB can use as a reference if interested. This is HSRB's final meeting report that includes the protocol review of study AHE120.</p>
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