UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 29, 2017

MEMORANDUM

SUBJECT: Ethics Review of Completed AHETF Study AHE170 on Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules

FROM: Michelle Arling, Human Research Ethics Review Officer
Office of Pesticide Programs (OPP)

TO: Dana Vogel, Director
Health Effects Division, OPP

Yu-Ting Guilaran, Director
Pesticide Re-evaluation Division, OPP

REF: Bruce, Eric D. (2017) Determination of Dermal and Inhalation Exposure to Workers During Open Pour Loading of Granules. Study Number AHE170, 841 p., October 3, 2017 (MRID 50419301)

Bruce, Eric D. and Holden, Larry R. (2017) Scenario Monograph Report. Agricultural Handler Exposure Scenario Monograph: Open Pour Loading of Granules. Report Number AHE1017, 258 p., October 25, 2017.

Bruce, Eric D. (2017) IRB Correspondence Report for Study AHE170. Related Submissions. Study Report AHE170 and Scenario Monograph Report No. AHE1017. 487 p., September 25, 2017. (MRID 50419302)

I have reviewed the available information concerning the ethical conduct of the research reported by the Agricultural Handler Exposure Task Force (AHETF) in the referenced documents. 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 pouring granular pesticide products into application equipment. The monograph report for the open pour loading of granules summarizes the dermal and inhalation exposure data collected through study AHE170 for the open pour loading of granules agricultural handler scenario.

In its conduct, study AHE170 met applicable ethical standards for the protection of human

subjects of research, and requirements for documentation of ethical conduct of the research were satisfied. Therefore, if study AHE170 and scenario monograph report AHE1017 are determined to be scientifically acceptable, I find no barrier in regulation to EPA's reliance on them in actions under FIFRA or §408 of FFDCA.

In addition, under 40 CFR 26.1604, EPA is required to seek input from the Human Studies Review Board (HSRB) for intentional exposure human studies covered by EPA's human studies rule that are initiated after April 7, 2006. EPA will share study AHE170, scenario monograph report AHE1017, the associated support documents, and EPA's science and ethics reviews of the study with the HSRB for their review. This memorandum and its attachments constitute EPA's ethics review.

Summary Characteristics of the Research

Study AHE170 developed data to determine the potential dermal and inhalation exposure for workers who conduct open pour loading of granular pesticides into pesticide application equipment. Additional tasks performed included stacking bags, loading and unloading bags from vehicles and storage, and any post-application equipment cleaning; application of pesticides was not included as a task monitored during this study. The dermal and inhalation exposure information was collected from workers conducting these tasks while wearing inner dosimeters (long underwear) under regular work clothes and air sampling pumps. In addition, researchers collected face and hand wipe samples from the subjects at the end of the workday as well as before any eating or smoking breaks.

A monitoring unit or MU refers to a single subject (worker) who is carrying out activities using a particular pesticide formulation under a specific scenario, on a particular day. For each MU in this study, the subjects conducted at least three loading events consisting of open pour loading of granules into application equipment. MUs also included other non-study work-related tasks, as well as breaks. Every MU provides an estimate of a single handler-day of exposure to the worker who open poured granular products into application equipment through measurement of the dermal and inhalation exposure potential for a single subject for a time period that represents a typical workday. A cluster is a group of MUs that are performed close together in terms of location and time. The AHE170 protocol, approved by Schulman Institutional Review Board (IRB), specified 21 MUs to be conducted, three MUs in each of seven geographic monitoring areas. The protocol was amended (Amendment 4, p. 440 of IRB Correspondence Report) to allow the final two MUs to be conducted in any monitoring area. Although a total of 21 subjects were enrolled in the study, valid total dermal exposure results are available for only 19 of the MUs conducted because the jars containing the hand wash samples collected for two MUs broke and it was not possible to analyze these samples.

The table below identifies the monitoring areas for the 21 MUs and the number of workers/MUs per monitoring area.

Monitoring Area Number	**States Included in Monitoring Area**	**Monitoring Units Conducted**
701	New York, Pennsylvania, Delaware, Maryland	1

702	Virginia, North Carolina, South Carolina, Georgia, Alabama	3
703	Florida	3 (1 valid; 2 incomplete due to broken hand wash sample jars)
704	Indiana, Ohio	3
705	Iowa, Illinois	3
706	Minnesota, North Dakota, South Dakota	4
707	Idaho, Eastern Washington, Eastern Oregon, Nebraska, Wyoming	4

Attachment 1 lists major study events in chronological order and attachment 2 identifies the surrogate active ingredients used in the study.

1. Value of Research to Society

This study developed data to determine the potential exposure of workers who manually open containers of granular pesticide products and open pour these granules into the appropriate application equipment using their normal work practices. This loading method is applicable to a large variety of commercially important crops and the existing exposure data are inadequate. EPA will use the results of this study to estimate the dermal and inhalation exposure likely for a wide range of agricultural pesticides loaded under this exposure scenario.

2. Subject Selection

a. Recruitment

According to the protocol and completed study report, "Recruiting activities occurred in three phases that are each described in detail in the sections below and can be summarized as follows:

- Phase 1: List growers and commercial applicators (i.e., employers) in the monitoring area (Universe List), and then identify those that are qualified for the study by calling them to determine whether they use granular pesticide products (Qualified List)
- Phase 2: Call qualified employers to determine those that might be willing to cooperate with the study by allowing AHETF to recruit workers to participate in the exposure monitoring study (Potentially Eligible List)
- Phase 3: Contact and visit potentially eligible employers, confirm eligibility (Eligible List) and then schedule and conduct monitoring of workers with experience loading granular products by open pouring." (p. 24, AHE170 Study Report)

The recruitment for Phase 1 used two methods for identifying employers: those referred to by AHETF by local agricultural specialists (LAS) or other employers/growers, and names from publicly-available sources that were then screened by a call center. In each of the monitoring areas, LAS and

growers were contacted for recommendations of potentially eligible employers, i.e., those likely to use granular pesticides. LAS and employers were requested to contact growers to get consent to share the referred grower's contact information with AHETF prior to the research staff making contact; however, the protocol was amended to allow AHETF to contact growers directly in instances where the referring party was not willing to make contact prior to AHETF (Amendment 2, pp. 422-423 of IRB Correspondence Report).

The table below summarizes the extent of the lists and numbers of monitoring units (MUs) for each original monitoring area in study AHE170. The study report provides specific details about the recruitment details by monitoring area (pp. 25-54, AHE170 Study Report)

Monitoring Area	**Employer Universe List**	**Qualified Employer List**	**Potentially Eligible Employer List**	**Eligible Employer List**	**MUs Collected**
701 = NY/PA	8,055	185	42	6	1
702 = AL to VA	10,145	35	14	8	3
703 = FL	3,971	39	8	6	3
704 = IN/OH	19,913	92	26	5	3
705 = IA/IL	44,376	41	16	9	3
706 = MN/ND/SD	41,378	156	37	8	4
707 = ID/WA/OR	15,557	108	25	9	4

The recruitment process discussed in the protocol for AHE170 references specific AHETF standard operating procedures (SOPs). These SOPs were previously reviewed by the HSRB. With regard to recruitment, the protocol references SOPs 11.B.7, 11.K.O, 11.L.O, and 11.M.O. When considered together, these SOPs discuss basic steps that were followed during the process of assembling lists and recruitment. The basic steps and where they are reflected in the AHE170 study report are listed below.

1. Assemble universe list (SOPs 11.K.O and 11.L.O) - reflected in recruitment Phase 1 in AHE170 study.
2. Randomly select subset as master list for screening (SOPs 11.K.O and 11.L.O) - reflected in recruitment Phase 1 in AHE170 study.
3. Third-party professional calling center screens master list (SOPs 11.K.O and 11.L.O) – reflected in recruitment Phase 1 in AHE170 study. This is discussed in detail in the study in the descriptions of recruitment for the seven monitoring areas (pp. 25-54).
4. Identify qualified list (SOPs 11.K.O and 11.L.O) - reflected in recruitment Phase 1 in AHE170 study.

   An IRB-approved letter introducing the AHETF and the proposed exposure monitoring study was sent to all employers on the qualified list before moving on to Phase 2. (p. 26, AHE170 Study Report)
5. AHETF contacts qualified growers/applicators (SOP 11.M.0) – reflected in recruitment Phase 2 in AHE170 study.

   As discussed in SOP 11.M.0, the caller used a "discussion guide" during the eligibility assessment call. The goal was to identify potentially eligible growers/applicators for the study. Growers/applicators/employers were asked for permission to recruit workers for the study.

Written assurance was obtained from each recruited employer that workers will not suffer consequences whether or not they decide to participate and will not be subject to coercion.

6. Recruit workers from the pool of eligible growers, applicators, employers (SOP 11.B.7, Section 4.2) and organize the recruitment meetings (SOP 11.B.7, Section 4.3) – reflected in recruitment Phase 3 in AHE170 study.

   The Study Director (SD) or designee recruited potential subjects from among those working for eligible growers. Potential subjects were screened to determine their eligibility (e.g., sufficient experience performing the tasks to be monitored). Recruitment meetings occurred in all monitoring areas included in the study and required information was covered. For this study, all recruitment and consent meetings were conducted in English. For the most part, recruitment meetings were conducted one-on-one; in one instance, 2 workers attended a recruitment meeting. At each meeting, the study, protocol, consent form, and eligibility criteria were discussed; the consent form and IRB-approved recruitment flyer were distributed; and workers were encouraged to take the consent form home for review.

   Consistent with the protocol, all growers signed the Employer Cooperation Statement (also known as the employer non-coercion statement) before any recruitment meetings affirming that they would not coerce or unduly influence their workers to either participate or not participate in the study. In some cases, the participant was the grower and signing the statement was not required. An informational flyer was used during the recruitment meetings with volunteers, which had been approved by Schulman IRB.

The consent process is discussed in more detail in Section 5 below.

b. Demographics

Following the recruitment process described in Section 2.a. above, 21 subjects were enrolled in the study. All subjects were male, and ages ranged from 20-78 years old. All subjects had experience performing the tasks to be monitored, open loading of granular pesticides, within the last year. Of the subjects, 11 were farm owners and 10 were farm employees.

Regarding the enrollment of all male subjects, AHETF confirmed EPA's understanding that there are not many females engaged in the types of activities monitored under this study. In an email to EPA, AHETF noted that:

- "No females ever gave consent to be in the study (however, the Study Director recalls one female who was willing to participate, but never gave consent as the other MUs in the monitoring area were conducted before that female's farm was ready to be planted).
- AHETF did not intentionally avoid females, nor alter any recruitment procedures that would impact recruiting males vs. females.
- AHETF simply did not find many females involved with planting activities or loading planters among the many employers contacted during recruitment for AHE170. This is simply a male-dominated activity, as was the case for most of the other pesticide handling scenarios in the AHETF monitoring program."

The study report includes additional information about the subjects monitored on pages 90-93.

c. Inclusion/Exclusion Criteria

Subjects met the inclusion criteria outlined in AHETF SOP 11.B, section 5. Subjects had

experience handling pesticides as part of their job, were trained in safe pesticide handling procedures, provided proof that the were at least 18 years old, confirmed that they were not an employee of a pesticide company, were in good health and had no medical conditions that would affect their ability to participate in the study. Subjects confirmed that they usually wore the personal protective equipment (PPE) required by the label, and were willing to wear the long underwear/inner dosimeter. One person who considered for enrollment in the study was found ineligible because he had insufficient experience performing the tasks to be conducted under the study.

3. Risks and Benefits

The risks of participation in the study included 1) the risk of heat-related illness, 2) the risk associated with scripting of field activities, 3) psychological risks, 4) the risk of exposure to surfactants, and 5) the risk of exposure to surrogate chemicals.

Risks to subjects were minimized by enrolling healthy subjects, enrolling subjects with experience performing the activities to be monitored, ensuring that subjects wore the PPE required by the product labeling, having medical personnel on-site during monitoring events, closely observing subjects for signs of heat-related illness, and reminding subjects of safe chemical handling practices and reviewing labeling use directions prior to monitoring events. All subjects wore a single layer of clothing (long pants and long-sleeved shirt) over the inner dosimeter, and wore either leather or chemical-resistant boots. Subjects using products containing chlorpyrifos also wore a filtering facepiece respirator provided by the employer, as required by the product's labeling. Tables summarizing the clothing and PPE worn by each subject are included in tables 4 and 5 on pp. 94-97 of the AHE170 Study Report.

AHETF has a specific SOP to address heat-related illnesses (SOP 11.G). This SOP was followed during the study to minimize the risks of heat-related illness. All researchers were trained to recognize the symptoms of heat-related illness, a medical professional (nurse, certified first responder, or emergency medical technician) was on-site for each monitoring event and checked subjects for signs of heat-related illness, and subjects were reminded to take breaks as necessary. The heat index was monitored based on measurements from the on-site weather station, and the maximum heat index of 105° was never reached. There were no reports of heat-related illness and no MU was stopped due to weather or heat-related symptoms.

The research offered no direct benefits to subjects. The primary benefit of the research is new data about the dermal and inhalation exposure of workers who perform open pour loading of granular pesticides. EPA and other regulatory agencies will use this information to support exposure assessments for a wide variety of pesticides with similar use patterns.

In this study, risks to subjects were minimized. The low residual risk was reasonable in light of the benefits to society from the new data supporting more accurate pesticide handler exposure assessments for a wide range of agricultural pesticides.

4. Independent Ethics Review

EPA and the HSRB reviewed the protocol for study AHE170 in 2014. The AHETF submitted the AHE170 protocol, approved by the overseeing Schulman Associates Institutional Review Board, Inc. (SAIRB), to EPA. The protocol and EPA's ethics review, dated October 8, 2014, were discussed

by the HSRB at its November 5, 2014 meeting. With regard to ethics, the HSRB's January 20, 2015 final meeting report concluded that, "If the research is performed as described, it is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L."[1]

AHETF did not need to make modifications to the protocol based on the reviews by the EPA and HSRB. Attachment 3 notes that neither EPA nor the HSRB made recommendations to AHETF related to the ethical conduct of the study. Schulman IRB notified AHETF that the protocol, consent materials, and sponsor letter were approved on June 30, 2014, and approved 4 subsequent amendments to the protocol between March 2015 and May 2016. There were 4 deviations reported to the IRB, as reflected in AHETF's chronology of major study events (pp. 8-14, IRB Correspondence Report).

Amendment 1 to the protocol was directly related to the ethical conduct of the study. This amendment added 2-4,D as an additional potential surrogate substance. This amendment was approved by Schulman IRB on March 26, 2015. This amendment updated the protocol to include 2,4-D but did not make a corresponding edit to the informed consent materials. (pp. 354-360, IRB Correspondence Report) The consent form lists the pesticides that might be handled as part of the study, but does not include 2-4,D:

> "*You will be asked to mix/load a pesticide product that is registered by the US Environmental Protection Agency (EPA) and the state where the application takes place. The product must contain one of the following ingredients: carbaryl, chlorpyrifos, dithiopyr, ethalfluralin, imidacloprid, mefenoxam, pendimethalin, permethrin, tefluthrin, or thiophanate-methyl. The label for that product will be reviewed with you prior to participation in the study. This review will include how much of that product you might handle during the study, the precautionary health statements on the label, what clothing and personal protective equipment you must wear, the importance of washing your hands before eating or smoking, and other safety precautions that should be followed. The label for this product will be on hand for you to look over and talk about at any time you want.*" (p. 465, IRB Correspondence Report).

AHETF confirmed that the failure to update the consent materials was an oversight.

One subject, M4, handled 2-4,D during this study. The consent form for this MU indicates that the subject was informed of the identity of the substance handled on the day of the monitoring event, April 4, 2015. (pp. 372-381, IRB Correspondence Report). In addition, a researcher reviewed the label for the product with the subject on the day of the monitoring event, so the subject was informed of the relevant labeling elements in addition to the identity of the surrogate substance. Although the failure to update the consent materials to reflect the addition of a surrogate substance constitutes an unreported deviation, the health and safety of the participating subjects was not put at risk as a result of this amendment or deviation.

The three other amendments to the protocol were related to AHETF researchers contacting growers or commercial applicators referred by another employer, adding new analytical methods for determination of ethalfluralin and tefluthrin residues in hand wash and face/neck wipe samples, and allowing the last 2 MUs to be conducted in areas other than the area originally anticipated. None of

[1] Parkin, Rebecca T. November 5, 2014 Human Studies Review Board Meeting Report. January 20, 2015. https://www.epa.gov/sites/production/files/2015-01/documents/hsrb-5-nov-2014-final-report.pdf

these amendments directly impacted the health, safety, or welfare of the subjects.

There were 4 reported deviations to the protocol. Deviation 1 reported a subject smoking a cigarette without first having his hands washed, and also loading pesticide-treated seed (outside the scope of the products monitored during this study) without wearing gloves required by the labeling. The failure to take a hand wash sample prior to MU1 smoking a cigarette was a researcher oversight. Regarding the loading of treated seed without proper PPE, AHETF SOP 10.C, Section 6.9 gives the Study Director discretion about how to handle practices that do not follow the labeling requirements, even for activities that are not part of the scripted monitoring. In this instance, because the seed was only loaded once and towards the end of the monitoring event, and because the study-specific guidance to researchers noted that [i]f a subject also loads seed into a planter, he may remove the extra PPE as long as the hopper lids are closed (and no PPE are required for loading seed)", there was no corrective action taken and no follow up with the subject. These deviations did not negatively impact the health, safety or welfare of the subject.

Deviation 2 included several elements. The ethics-related deviation reported occurred when the researchers provided 2 subjects (M7 and M9) with nitrile gloves, rather than the gloves listed on the product labeling (barrier laminate and viton). Neither subject reported adverse effects as a result of this glove substitution. This deviation did not affect the health, welfare or rights of the subject.

Deviation 3 covered several monitoring areas and 2 different elements. One element was related to the ethical conduct of the study. The pump for M17 would not stay on and was changed after 96 minutes of monitoring. However, the flow rate of the old/broken pump was not measured. This deviation did not affect the health, welfare or rights of the subject.

Deviation 4 reported use of the proper analytical method to analyze whole body dosimeters for permethrin content; however, the protocol had not been amended to reflect the proper analytical method before it was used. This did not affect the health, welfare or rights of the subjects.

Schulman IRB approved the close-out of AHE170 on September 8, 2016.

5. Informed Consent

All participating subjects completed the informed consent process and signed the consent form. The most recent version of the informed consent form was approved by Schulman IRB on June 24, 2014 and dated May 17, 2016. (pp. 462-471, IRB Correspondence Report). All consent meetings were done privately with only the potential volunteer and SD or designee present, and all meetings were conducted in English. Consent occurred after the recruitment meeting and prior to monitoring. During the consent meeting, the SD or designee met privately with the volunteer and went through the informed consent document section by section. The SD or designee ensured that the volunteer understood the contents of the consent form before requesting consent.

The protocol allows for the researcher to read the consent form to non-readers and to have someone present during the consent meeting. For study AHE170, there were no interested workers who were non-readers. The protocol also directs that accommodations will be made for bilingual researchers who must be present if the preferred language is Spanish. However, in this study, all interactions were conducted in English.

6. Respect for Subjects

Subjects' identifying information was kept confidential. Subjects were offered the opportunity to request their personal monitoring results and information about the study. AHETF confirmed that this information was provided to each of the subjects who made such a request. A sample letter providing the results is included as Attachment 4.

Each subject received compensation consistent with the protocol and informed consent document. Compensation was $20 for participating in the consent meeting and $80 for each day of participation in the study, regardless of whether or not the subject withdrew or was removed from the study. No subjects withdrew or were removed from participation in this study.

Completeness of Submission

The submission by AHETF and additional materials provided by Schulman IRB satisfy the requirements of §26.1303. A checklist indicating how each requirement has been satisfied is provided in Attachment 5.

Applicable Ethical Standards

The following provisions of 40 CFR 26 Subpart Q define the applicable ethical standards which read in pertinent part:

> **§26.1703**: Except as provided in §26.1706, EPA shall not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.
>
> **§26.1705**: Except as provided in §26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with all applicable provisions of subparts A through L of this part.

In addition, §12(a)(2)(P) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) applies. This passage reads:

> In general, [i]t shall be unlawful for any person . . . to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

Prohibition of research involving intentional exposure of pregnant or nursing women or of children

40 CFR §26.1703 prohibits research involving intentional exposure of pregnant or nursing women or of children under 18. All subjects who participated in study AHE170 were male and at least 18 years old. Therefore, 40 CFR §26.1703 does not prohibit reliance on this research.

Substantial compliance with 40 CFR 26 subparts A through L

40 CFR §26.1705 requires that EPA have "adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part." Within this range, only subparts K and L are directly applicable to the conduct of third-party research such as this. The AHE170 study was conducted in substantial compliance with subparts K and L.

Compliance with 40 CFR §26 subpart M

As documented in attachment 5 to this review, the central requirements of 40 CFR §26 subpart M, §26.1303 to document the ethical conduct of the research were addressed.

Compliance with FIFRA §12(a)(2)(P)

The requirement of FIFRA §12(a)(2)(P) that human subjects of research be "fully informed of the nature and purposes of the test and of any physical and mental health consequences reasonably foreseeable therefrom," and "freely volunteer to participate in the test," was met for this study.

Conclusion

This study reports research conducted in substantial compliance with the requirements of 40 CFR 26 subparts A through L. In its conduct, study AHE170 met applicable ethical standards for the protection of human subjects of research, and requirements for documentation of ethical conduct of the research were satisfied. From EPA's perspective, if this study is determined to be scientifically valid and relevant, there is no regulatory barrier to EPA's reliance on it in actions under FIFRA or §408 of FFDCA. This research will also undergo review by the Human Studies Review Board.

cc: Rick Keigwin
Matt Crowley
Jeff Dawson
David Miller
Dana Friedman

Attachment 1: Major AHE170 study events in chronological order
Attachment 2: Surrogate active ingredients used in study AHE170
Attachment 3: Sample Letter Reporting Study Results to Subjects
Attachment 4: AHETF actions in response to EPA and HSRB comments on protocol
Attachment 5: §26.1303 Completeness checklist for AHE170 Study

Attachment 1

Note: This is excerpted from pp. 86-87 of the AHE170 Study Report.

Table 1. Chronological Listing of Major Study Events

Date (m/dd/yy)	**Major Study Events Related to Collection of MUs**
5/16/14	Initial submission of AHE170 protocol and related materials to Schulman Associates Investigational Review Board, Inc. (SAIRB) for review
6/30/14	Initial Approval by SAIRB of final AHE170 protocol and related materials (English only)
7/14/14	Approval by SAIRB of Spanish recruitment documents
11/5/14	Review of protocol and related materials by Human Studies Review Board (HSRB)
12/5/14	Protocol signed by Study Director
12/15/14	Start of Phase 1 recruiting, calling employers to determine Qualified Employers from initial list of growers (in Area 703 = FL)
2/23/15	Start of Phase 2 recruiting, calls to Qualified Employers from Primary and Secondary sources (in Area 703 = FL)
3/3/15	Start of Phase 3 recruiting, calls to Potentially Eligible Employers, site visits, and participant selection (in Area 703 = FL)
3/26/15	Approval of Amendment 1 by SAIRB (add 2,4-D as surrogate)
4/14/15	Submission of Deviation 1 to SAIRB
4/28/15	Approval of Ongoing Research by SAIRB (i.e., annual renewal)
3/19/15	Collection of MU M1
3/21/15	Collection of MU M2 field fortifications applicable to M1 and M2
4/2/15	Collection of MU M3 and field fortifications
4/4/15	Collection of MU M4 and field fortifications
4/28/15	Collection of MU M5
5/1/15	Collection of MU M6 and field fortifications
5/3/15	Collection of MU M7 and field fortifications applicable to M5 and M7
5/14/15	Collection of MU M8 and field fortifications
5/19/15	Collection of MU M9 and field fortifications
6/2/15	Collection of MU M10 and field fortifications
8/18/15	Collection of MU M11 and field fortifications

2/11/16	Submission of Deviation 2 to SAIRB
4/8/16	Approval by SAIRB of Amendment 2 (allow immediate contact of referrals)
4/14/16	Collection of MU M12 and field fortifications
4/15/16	Approval of Ongoing Research by SAIRB (i.e., annual renewal)
4/20/16	Collection of MU M13
4/21/16	Collect field fortifications applicable to M13 and M16
4/22/16	Collection of MU M14 and field fortifications
4/23/16	Collection of MU M15 and field fortifications
4/25/16	Collection of MU M16
5/3/16	Approval by SAIRB of Amendment 3 (new analytical method for tefluthrin)
5/6/16	Collection of MU M17 and field fortifications applicable to M17, M18, and M19
5/7/16	Collection of MUs M18 and M19
5/10/16	Approval by SAIRB of Amendment 4 (allow up to 5 MUs per monitoring area)
5/16/16	Collection of MU M20
5/18/16	Collection of MU M21 and field fortifications applicable to M20 and M21; end of recruitment efforts
11/18/16	Submission of Deviation 3 to SAIRB
3/2/17	Submission of Annual Renewal to SAIRB
4/3/17	Approval of Ongoing Research by SAIRB (i.e., annual renewal)
4/10/17	Analytical Report finalized for 2,4-D
3/24/17	Analytical Report finalized for pendimethalin
5/24/17	Analytical Report finalized for chlorpyrifos
6/28/17	Analytical Report finalized for tefluthrin
6/30/17	Analytical Report finalized for permethrin
9/8/17	Close-Out Letter from SAIRB

Attachment 2
Surrogate Active Ingredients Used in AHE170

Note: This is a summary based on the table on pp. 88-89 of the AHE170 Study Report.

The following surrogate active ingredients listed in the protocol were used during the study. The following list identifies how often each of the protocol-specified surrogates was used. This is a summary based on pp. 88-89 of the study report.

Surrogate	**Number of MUs Using Surrogate**	**Product Name**	**EPA Reg. No.**
Tefluthrin	10	Force 3G	100-1075
Tefluthrin	1	Precept Insecticide	100-1075-524
2,4-D	1	2,4-D Granules	228-61
Pendimethalin	1	Pendulum 2G	241-375
Chlorpyrifos	4	Chlorpyrifos 15G	19713-505
Chlorpyrifos	3	Lorsban 15G	62719-34
Permethrin	1	Pounce 1.5G	279-3059

Attachment 3
Ethics Comments from November 2014 HSRB Meeting & AHETF Actions

EPA Comments on AHEA170 Protocol	**AHETF Actions to Address Comments**
EPA had no recommendations on the protocol for AHE170	N/A
HSRB Comments on AHE170 Protocol	**AHETF Actions to Address Comments**
The HSRB had no recommendations on the protocol for AHE170	N/A

Attachment 4
Sample Letter Reporting Study Results to Subject

AGRICULTURAL HANDLER EXPOSURE TASK FORCE

Toll-Free Phone Number: (866) 925-1421 (24-hour service in English or Spanish)

[Name and Address Redacted]

June 26, 2017

Dear [Name Redacted]:

The Agricultural Handler Exposure Task Force (AHETF) again thanks you for being in the study of workers that loaded granules from bags by open pouring. You participated in this study near Kersey, PA on May 14, 2015 and you requested information on your level of pesticide exposure. Attached is a summary of your personal dermal exposure results.

As you may recall, we measured the amount of pesticide that was found on the long underwear we asked you to wear under your clothes. We also measured the amount of pesticide that could be washed from your hands and wiped from your face and neck. Added together, we call this "Total Dermal Exposure".

Of the 21 people monitored across the country, we have valid dermal exposure results for 19 and have summarized the data. The summary shows which of your body parts got the most pesticide on them. It also tells you how your level of dermal exposure compares to the other workers.

If you have any questions about your exposure results or anything else in this letter, feel free to call me directly on my cell phone:

[redacted] (Eric Bruce, Study Director)

Thank you again for being in this study.

Sincerely,

_____

Eric Bruce
Study Director

YOUR PERSONAL AND GROUP DERMAL EXPOSURE RESULTS

Figure A shows what percentage of your total dermal exposure was on various body parts.

For comparison, Figure B shows the same information for the group as a whole.

Figure A
Your Personal Exposure Results

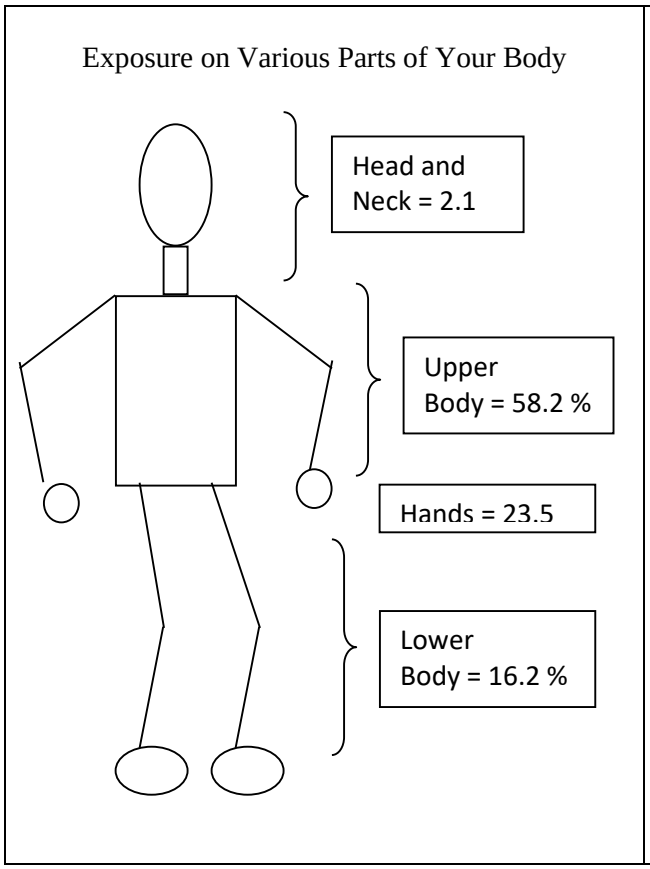
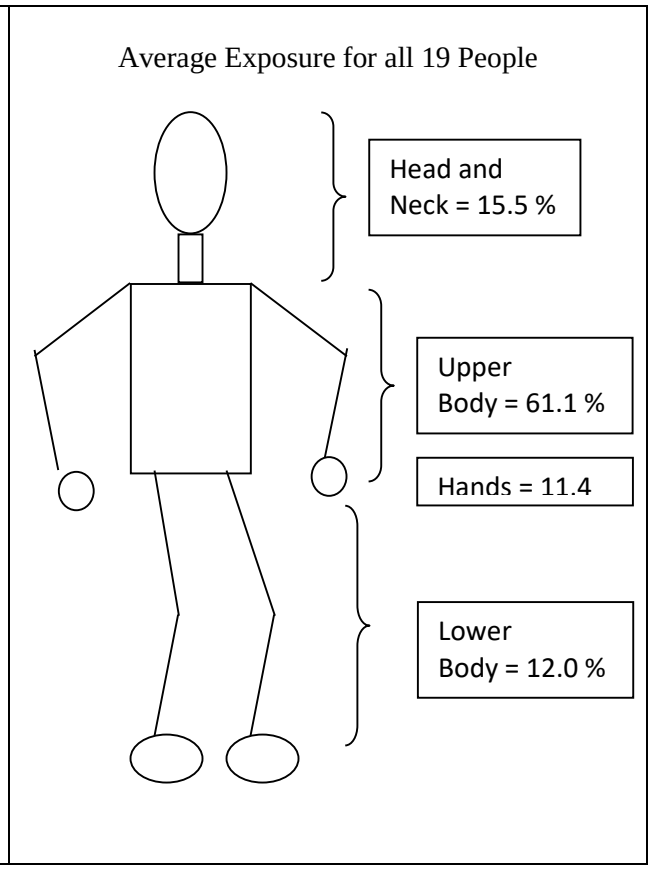


Figure B
Exposure Results for Entire Group



Your total dermal exposure ranked as **Number 5** of the 19 people that were involved in the study for open pour loading of granules. The highest exposure has a rank of 1 and the lowest has a rank of 19. This means only a few of the other workers had a higher measured exposure than you.

Most of the pesticide found was on your upper body, probably because you picked bags up against your body and poured granules right in front of your upper body. In addition, your hands and lower body had a larger percentage of exposure than most workers.

During the study, we observed that most granules are somewhat dusty and we suspect that dust is the primary cause of pesticide residues getting through the clothing. When pouring granules, you should be careful to minimize dusting by pouring carefully and try to stand upwind of the hoppers you are loading.

You should remember to always wear long sleeves, long pants, and gloves when loading granules. You should also remember to bathe/shower and wash your clothes promptly after loading granules.

WHAT YOUR PERSONAL EXPOSURE RESULTS MEAN

If your dermal exposure was generally higher than others in the study, then you should try to do things that lower exposure. You should pay more attention to your work habits and learn to improve them. Guidance on selecting and using personal protective equipment is in the paper from EPA that is in this mailing.

If your dermal exposure was generally lower than others in the study, then you should continue using good habits that reduce your exposure. Do not become careless in your work practices, since attention to small details can reduce your exposure. Of course, the goal for all pesticide handlers is to reduce exposure to **a minimum**.

Attachment:

Protect Yourself - Brush Up On Covering Up

Attachment 5
§ 26.1303 Checklist for Completeness of AHE170 Submitted for EPA Review

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

Requirement			Y/N	Comments/Page References
(a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB	§1115(a)(1): Copies of • all research proposals reviewed, • scientific evaluations, if any, that accompany the proposals, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y	
	§1115(a)(2): Minutes of IRB meetings which shall be in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.		Y	
	§1115(a)(3): Records of continuing review activities.		Y	
	§1115(a)(4): Copies of all correspondence between the IRB and the investigators.		Y	
	§1115(a)(5): • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution		Y	
	§1115(a)(6): Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).		Y	EPA received this previously.
	§1115(a)(7): Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).		n/a	Subjects received personal exposure results.
(b) Copies of all of the records relevant to the information identified in §26.1125(a)-(f)	§1125(a) A discussion of:	(1) The potential risks to human subjects;	Y	
		(2) The measures proposed to minimize risks to the human subjects;	Y	
		(3): The nature and magnitude of all expected benefits of such research, and to whom they would accrue;	Y	
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	
		(5) The balance of risks and benefits of the proposed research.	Y	
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	
	§1125(f): Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.		Y	
(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research			Y	
(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.			n/a	