

US EPA ARCHIVE DOCUMENT

Agricultural Handler Exposure Task Force (AHETF)

May 12, 2009

MEMORANDUM

SUBJECT: AHETF Response to EPA Science and Ethics Review (4/8/2009) of AHETF Scenario Design and Protocol AHE120 for Exposure Monitoring of Workers during Mixing and Loading of Pesticide Products in Water Soluble Packets in Five Regions of the United States.

FROM: Richard H. Collier, Ph.D.
Chair, AHETF Administrative Committee

TO: Steve Knizner, Associate Director
Health Effects Division
United States Environmental Protection Agency

REF: Bruce, E. (2009) Determination of Dermal and Inhalation Exposure to Workers during Mixing/Loading of Pesticide Products in Water Soluble Packets in the United States. Unpublished protocol dated December 11, 2008, prepared for the Agricultural Handler Exposure Task Force under Sponsor ID AHE120, 552 p.

The AHETF read the EPA report on the above referenced protocol. In the ethics section of the report, EPA stated that before the research is conducted, the protocol should be revised as follows and resubmitted for review by the approving IRB:

- Principle Field Investigators are identified in the protocol. Local Site Coordinators (if used) and analytical laboratories will be identified in the protocol by amendment.
- The page headings on the English Language Research Participant Bill of Rights should be changed from Spanish to English.

In addition, EPA requested that the AHETF provide the following information:

- Collect information on growers who do not respond or who decline to participate, such that the representativeness of participating growers can be evaluated.

- Provide more information about how individual level exposure data will be presented to subjects upon request. In particular, please explain how the data will be framed and how the AHETF will work to prevent workers from changing future behavior to their own detriment if their individual risk levels are lower than the average of all workers.
- Verify the appropriateness of, or make necessary improvements to, the Spanish translations of the consent form, product risk statements, and recruitment materials. Spanish translations should be written in common, simple Spanish, appropriate to the reading ability of potential Spanish-speaking subjects.

This memorandum explains what the AHETF has tried in the past and what it proposes to do in the future to address these issues.

Identification of Field and Analytical Members of the Research Team

All members of the research team will be identified by an amendment to the protocol. The protocol was written in December of 2008. Because of the time required for reviewing and approving the protocol, plus the need to conduct the study during the growing season, it will not be possible to conduct the study until 2010. It is difficult to identify the field and analytical laboratories a year and a half in advance of study initiation.

Page Headings on the English Language Research Participant Bill of Rights

The heading was inadvertently mislabeled and will be corrected. Both English and Spanish versions of the document will be prepared for use, as appropriate, when interviewing the study participants.

Representativeness of Participating Growers

Summary

The concern expressed by the HSRB at their October 2008 meeting is related to evaluating whether study participants are representative of the applicable population of growers or commercial applicators. The HSRB idea of comparing the characteristics of growers who could not be contacted during the recruiting process with the Eligible growers was tried but was not successful. People who could not be contacted initially still could not be contacted later even after 20 attempts.

The AHETF then modified its approach by comparing the characteristics of Eligible growers who were potential participants with the characteristics of Eligible growers who were not interested in being considered. This was successful, but did not include data from non-contacted growers and thus did not provide information on the real concern about the

differences between the Eligible growers and growers who could not be contacted. This led to the proposal explained below of characterizing the Eligible growers and then asking experts how those characteristics compare to all growers in the area where the study was conducted.

Following the June 2009 HSRB meeting, the protocol will be amended to explain the approach that will be taken to address the representativeness of the Eligible growers in the WSP mixer/loader study.

Recruitment Process

The AHETF recruitment process consists of assembling a “Master List” of growers or commercial applicators that are qualified through a professional calling service. This screening produces a “Qualified List” of growers or commercial applicators that meet the basic acceptance criteria for consideration as study participants.

A knowledgeable member of the research team calls all of the names on the Qualified List, tells them about the study and asks if they would consider being a participant. Those who respond affirmatively are put on the “Potential Eligible List” and then visited by the Study Director. Those that still agree to participate make up the “Eligible List” from which the final five participants are chosen.

Past Attempts

The HSRB suggested that AHETF try to get information on the characteristics of growers or commercial applicators who could not be contacted during the recruitment process. The AHETF attempted this in a couple of ways as explained below.

AHETF conducted two airblast applicator studies in 2008 – one on pecans and the other on citrus. Following the completion of those studies, the AHETF administered a post-study survey by making up to 20 calls to each of the names on the Master List who were not contacted during the recruitment process. Out of a total of 198 non-contacts, AHETF was able to contact only 18 growers using this procedure. The results showed that the AHETF recruitment procedure did a reasonably good job of contacting potential participants. The follow up response rate was too low for making any reliable comparison between the contacts and non-contacts. Trying to get in touch with non-contacts was difficult if not impossible.

The AHETF then made a comparison of the growers on the Qualified List who responded affirmatively to be considered as a potential participant with those who declined to be considered any further. The results from recruitment efforts for an upcoming airblast applicator study on cherries, as an example, indicated that the characteristics of 33 growers who showed a willingness to cooperate were very similar to the 40 growers who were not interested in being a participant. This approach worked well, but did not include information from non-contacts, and thus did not fulfill the ultimate objective of comparing the characteristics of the Eligible growers with the characteristics of the overall target population of growers or commercial applicators.

Proposed Approach for the WSP Mixer/loader Study

This present proposal is to characterize the Eligible growers and then ask experts how those characteristics compare to all growers in the area where the study was conducted. More specifically, the AHETF proposes the following procedures for the WSP mixer/loader study.

1. The professional calling center will ask all growers on the Master List the following qualifying questions:
 - Total number of crop acres farmed
 - Number of employees who are applicators
 - Whether pesticides are applied by self, employees or a commercial applicator
 - Whether they use any pesticides packaged in WSP
 - If so, whether they use the AHETF surrogates carbaryl or acephate
 - What crops these products are used on
 - What time of year the products are applied
2. At the completion of the study, summarized data from the growers on the Eligible List from which the final five were chosen will be sent to a couple of local experts (e.g., extension personnel, vocational agriculture instructors, dealers, etc.).
3. The experts will be asked:
 - Are the characteristics of the Eligible growers typical of all growers in the area where the study was conducted?
 - If not, how are the Eligible growers unusual for each characteristic?
 - Would you expect any differences in the way the Eligible growers handle pesticides?

With the benefit of the HSRB's advice at their June 2009 meeting, the WSP mixer/loader protocol will be amended to explain the approach that will be taken to address the representativeness of the Eligible growers.

How Individual Exposure Data will be Conveyed to Study Participants

During the consenting process, workers are given the opportunity to request their results from the study. The information needs to be conveyed in simple language that the workers can understand and include ways they might improve how they handle pesticides to reduce exposure. Special attention will be given to workers who have relatively low exposure to ensure the letter conveys the importance of continuing to be diligent in the handling of pesticides.

The letter will be sent to each of the participants as soon as the results for a cluster are known. This means the results for any given worker will be compared to the other four workers in that cluster. This will also ensure timely notification to the workers as opposed to waiting until all results for the study are known. A draft generic version of this letter is attached as Appendix A.

Spanish Translations

There is concern that documents translated into Spanish should reflect any specific terminology and wording common to the area where the study will be conducted. A single translator may not be familiar with all agricultural terminology or slightly different ways of wording the text. The AHETF will be conducting studies in virtually all agricultural regions of the country. Therefore, the AHETF proposes the following steps for localizing the Spanish Informed Consent Form and other related documents:

1. AHETF will contact people in several regions of the country who work closely with Spanish speakers through bilingual pesticide safety training, either through their state university (including direct contact with extension services) or at the state level such as with their department of agriculture.

A representative state will be chosen for each of seven broad regions of the country (West, Southwest, Northwest, Northeast, South, Southeast and Midwest). The following states have been tentatively selected based on their Hispanic populations and likely location of future AHETF studies: California, Texas, Washington, New York, Florida, North Carolina, and Michigan. The final states cooperating in this review project are, however, subject to change based on actual availability and/or cooperation by reviewers contacted.

2. AHETF will send the reviewers a generic version of an Informed Consent Form, a Product Risk Statement, a Recruitment Flyer, and the Employer Cooperation Statement. They will be asked to suggest any edits or changes in wording that would improve the understanding of the documents by Spanish-speaking workers in their area.
3. AHETF will also send the reviewers a list of agricultural terms (in English) that may be used in future protocols. AHETF will ask the reviewers to suggest the most appropriate translations for those terms.
4. Based on the comments received, AHETF will modify the documents to reflect the most appropriate translations for the study.
5. The AHETF versions of the documents, in both English and Spanish, will then be sent to the IIRB with a request to review and certify the submitted Spanish documents. The agricultural terminology that was verified to be appropriate will be highlighted as an aid to the translator who reviews and approves the Spanish documents for IIRB.

The AHETF proposes to follow this basic procedure for all future studies where there may be Spanish speakers. This approach allows the AHETF to localize the translated documents and avoids the requirement of any single translator to be knowledgeable about agricultural terminology in all parts of the country.

Study Worker ID: _____

Appendix A

***SAMPLE LETTER FOR INFORMATION PROVIDED TO PARTICIPANTS
REQUESTING PERSONAL EXPOSURE DATA***

<date>

<Worker name and address>

Dear <name>,

The Agricultural Handler Exposure Task Force (AHETF) again thanks you for being in the study of workers that <describe task> at <site> on <dates>. A total of <5> people were in your group. Here are your exposure results.

If you have any questions about your exposure data or anything else in this letter just call the AHETF toll-free number:

(866) 925-1421 (24-hour service in English or Spanish)

Thank you again for being in this study.

Sincerely,

<name>

Study Director

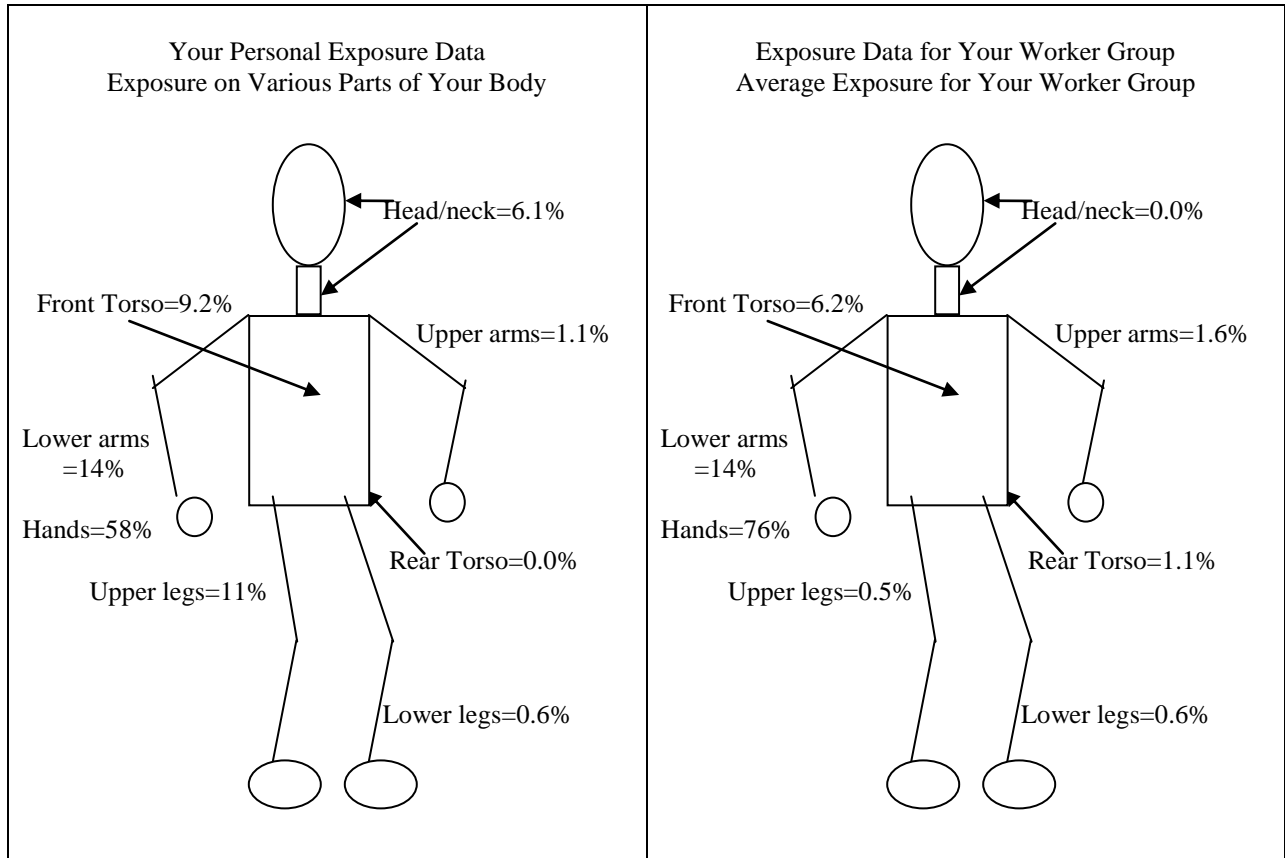
Study Worker ID: _____

YOUR PERSONAL AND GROUP EXPOSURE DATA

The numbers in Figure A are the percent of exposure to various parts of your body. The numbers in Figure B are the average percent exposure for all the workers in your group.

Figure A

Figure B



<Your head/neck exposure was higher than the group average. It was observed that you touched your face with your gloved hand several times during the day. That could account for the increased exposure.>

Your total exposure was ranked as the <second> highest exposure of the <five> people that were in your group.

Study Worker ID: _____

WHAT YOUR PERSONAL EXPOSURE DATA MEAN

If your 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. Some ideas on how to improve your work practices are in the other paper from EPA that is in this mailing.

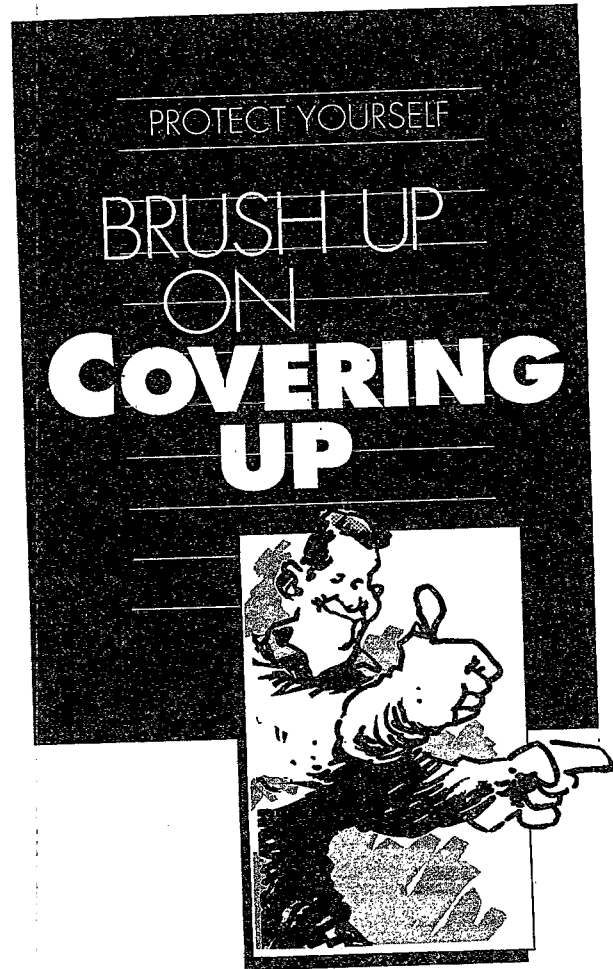
If your exposure was generally lower than others in the study, then you should continue using good habits that reduce your exposure. Do not become careless in your work practices, since attention to small details can reduce your exposure. Of course, the goal for all pesticide handlers is to reduce exposure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

Attachment:

Protect Yourself - Brush Up On Covering Up

Protection for Pesticide Handlers

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Washington, DC 20250



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COVERALLS



Some pesticide labels require a long-sleeved shirt and long pants of sturdy, woven fabric.

Many pesticide labels require coveralls worn over shirt and pants. Coveralls may be of woven or nonwoven fabric.

A few pesticide labels require chemical-resistant suits. The seams should be sealed.



COVERALL MATERIALS

Look for These Characteristics

woven Fibers: cotton or cotton/polyester
Weight: 7-10 oz.
Weave: twill (denim, chino, drill)



nonwoven Fabric made by bonding fibrous webs

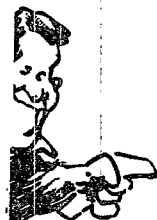


chemical-resistant Plastic or rubber materials or fabrics coated with plastic or rubber



SHOP FOR FIT AND FUNCTION

- Before buying, try on coveralls with garments you intend to wear under them.
- Zippers with overlapping flaps are preferred.



Protection for Pesticide Handlers

The information in this brochure is reproduced from a table-top exhibit consisting of eight 22" by 40" panels. Each page in this brochure is a panel on the exhibit. Each exhibit panel holds a different personal protective equipment guidance brochure containing further information.

The guidance brochures relate to personal protective equipment (PPE) and include:

- Coveralls, Gloves, and Other Skin Protection
- Clothing Layers for Added Protection
- Choosing Chemical-Resistant PPE
- Protective Eyewear
- Respirators
- Inspecting, Maintaining, and Replacing PPE
- Avoiding Heat Stress

The personal protective equipment exhibit and guidance brochures are located in the pesticide program office in each EPA region and state land-grant university. Contact your region or state for further information.

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CLOTHING LAYERS



1. Layer coveralls over shirt, pants, and underwear when the pesticide label requires it, or when you need extra protection.

2. Add a chemical-resistant apron when mixing and loading pesticides or cleaning equipment.

- Sleeveless aprons protect against spills and splashes to the body front.
- Aprons with sleeves—but open in the back—reduce exposure to the shoulders, arms, and body front.



USE CLOTHING LAYERS to increase protection.

REMEMBER—

- Hoods and wide-brimmed hats protect the neck and head.
- Unused hoods should be tucked inside the neckline so they don't collect pesticides.
- Sleeve guards protect arms.
- Reserve one or two sets of clothing for pesticide tasks.

REDUCE HEAT STRESS



RECOGNIZE THE SIGNS AND SYMPTOMS.

- Muscle spasms
- Excessive fatigue
- Heavy sweating
- Dizziness and confusion
- Nausea
- Unconsciousness

FOLLOW THESE GUIDELINES

to lessen the discomfort and health hazard of wearing protective gear in warm conditions.

Adjust gradually to working in the heat.

Drink plenty of water.

Take regular breaks in the shade.

Avoid the noonday sun by scheduling work for cooler times of the day.



WARNING: In case of severe symptoms, seek medical help. The cause could be heat stress or pesticide poisoning.

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CHEMICAL-RESISTANT GLOVES

WEAR CHEMICAL-RESISTANT GLOVES *when the pesticide label requires it.*



WHAT IS CHEMICAL RESISTANCE?

It means no movement of pesticides through the protective material during its use.



REMEMBER—

- Never place contaminated hands in gloves.
- Never wear leather, fabric, or fabric-lined gloves.
- Use gloves that extend at least to the mid-forearm.
- Consider shoulder-length gloves or gloves and chemical-resistant sleeve guards for mixing and loading.
- Replace gloves often.

WASH GLOVES THOROUGHLY BEFORE REMOVING THEM,

THEN WASH YOUR HANDS.



WORKING WITH LIQUID CONCENTRATES?

Wear nitrile, butyl, or barrier-laminate gloves, unless the label directs otherwise.

CLEAN AND INSPECT YOUR GEAR

1. Wash garments before reuse.

The best policy is to launder coveralls and work clothes daily. Pretreat soiled areas with a liquid detergent, wash with detergent in hot water, and line dry outdoors.



2. Clean other protective equipment by hand.

Wash rubber and plastic equipment inside and out with detergent, rinse well, and air dry.



3. Inspect gear for leaks, holes, tears, or worn places.



REMEMBER—

- Always wash pesticide clothing separately from the family laundry.
- Smell clothes after laundering. If pesticide odors are detected, rewash garments.
- Some contaminated garments may need multiple washings or may need to be discarded.
- Allow protective gear to air for 24 hours if possible after washing.

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PROTECTIVE EYEWEAR



WEAR
PROTECTIVE EYEWEAR *when the pesticide label requires it.*

CONSIDER
PROTECTIVE EYEWEAR *when dusts, mists, or splashes can get in your eyes or when working with pressurized systems.*



1. Goggles are acceptable eyewear for all pesticide handling situations and may be required on some pesticide labels. Goggles provide better eye protection than safety glasses or face shields.

2. Face shields protect the eyes and face from splashes. In severe exposure situations, a face shield may be worn over goggles.

3. Safety glasses with side shields and brow guards are acceptable in many situations.

REMEMBER—

- Avoid wearing contact lenses when handling pesticides.
- Use a full-face respirator to protect eyes, face, and respiratory tract or select eyewear that fits well with half-face respirators.

RESPIRATORS

WEAR A RESPIRATOR *when the pesticide label requires it.*



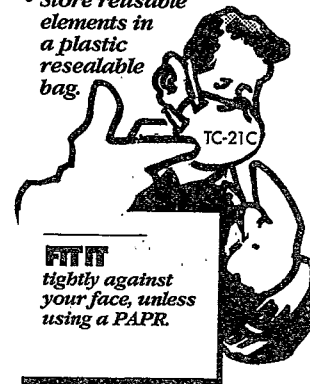
1. Dust/mist filtering respirators protect against dusts, powders, mists, and sprays. Look for NIOSH/MSHA approval number prefix TC-21C.

2. Vapor-removing respirators protect against gases and vapors. Choose
—a cartridge approved for organic vapors plus a pesticide prefilter; both with NIOSH/MSHA approval number prefix TC-23C; or
—a canister approved for pesticides/organic vapors with NIOSH/MSHA approval number prefix TC-14G.

3. Powered air-purifying respirators (PAPR) (positive pressure) protect without a tight seal. They are essential when facial hair would prevent other types of respirators from forming a tight seal.

REMEMBER—

- Replace the dust/mist filters immediately if breathing becomes difficult.
- Replace dust/mist or vapor-removing elements after each day's use unless the manufacturer or pesticide label directs otherwise.
- Replace vapor-removing cartridge/canister immediately if any taste, odor, or irritation is detected.
- Store reusable elements in a plastic resealable bag.



FIT IT
tightly against your face, unless using a PAPR.

(4)

(5)