Agricultural Handlers Exposure Task Force (AHETF) Study No. AHE38 Protocol Review
Airblast Application To Orchard Crops In The GA or FL Using Closed Cabs/Open Pour Liquid Mixing Protocol
Agency Reviewers: Jeff Evans & Jeff Dawson (Date of Review: 5/31/2006)

STUDY TYPE: Mixer/Loader/Applicator Passive Dosimetry Study Based On Whole-Body Dosimetry & Handwashing Techniques

TEST MATERIAL: Sevin ® Brand XLR Plus Carbaryl Insecticide
EPA Registration Numbers: 264-3333
Lot & Container Descriptions: To be recorded at field site.
Common Chemical Name Of Active Ingredient: carbaryl
CAS Number of Active Ingredient: 63-25-2
Nominal concentration of active ingredient: 4 lb ai/gallon

[In this study, the stability of the active ingredient in storage and a purity analysis of the formulated products will be conducted and tracking/storage conditions will also be documented. A sample will be retained as well for future needs.]

SYNONYMS: Carbaryl

CITATION: Determination of Dermal and Inhalation Exposure To Workers In Georgia or Florida During Applications To Orchard Crops Using Closed Cab Airblast Equipment And During Open Pour Mixing/Loading A Liquid Pesticide Product

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EXECUTIVE SUMMARY:

This study is part of a series of studies that are to be conducted by the Agricultural Handlers Exposure Task Force (AHETF). The premise of the AHETF is that data from these studies can be used generically by various stakeholders (e.g., applicants, registrants, EPA, and others) for calculating exposures for the occupational handlers of pesticides. Given this context, this protocol defines only this particular AHETF study to quantify exposures for those who apply liquid spray solutions to orchard crops (e.g., pecans, citrus or peaches) using closed cab airblast equipment. If possible, mixer/loader exposure using the liquid (i.e., Sevin XLR) products and open pouring techniques will also be monitored if the situation is feasible for such occurrences. [Note: Additional information concerning the overall scope of the AHETF is available that illustrates how this particular study will be integrated in the resulting database to be used for calculation of pesticide handler exposures.] The Agency believes these data are necessary because they will provide a means for considering current agricultural practices, equipment and techniques in its assessments allowing for more refined results. The monitoring techniques to be used for this study also have been standardized within the context of the AHETF which will provide a similar basis for analyzing trends in exposure compared to currently available data which can be confounded because of monitoring technique issues (i.e., disparity amongst studies). More refined data will allow the Agency to better establish the sensitivity of worker exposure levels to changes in various factors such as the amount of active ingredient handled, type of application equipment used, application rate used, volumes handled, and personal protective equipment used (i.e., data will allow for a better evaluation of exposures as a function of many variables to be measured during the conduct of this study).

The primary objective of this study is to collect up to 8 replicates of individuals conducting airblast applications to orchard crops (e.g., pecans, citrus, peaches) in full foliage, using closed cab tractors. Each applicator will make at least three applications representative of a full day's work. The exposure duration is meant to be for approximately 4 hours. The secondary objective of the study is to monitor workers mixing/loading liquid pesticide products using open mixing techniques (i.e., a possible number of mixer/loader replicates was not specified). Depending on the crop to be treated, application rates will range from approximately 3 to 5 pound active ingredient per acre in 100 to 300 gallons of water per acre. Field investigators will monitor actual agricultural practices so the nature of the situations to be monitored will depend somewhat on the agricultural requirements for those situations thus necessitating flexibility in the design of this study. An example scheme which illustrates the range of practices AHETF is attempting to capture in this study is presented below (based on their example from the protocol):

Replicate No.	Crop	Rate (lb ai/acre)	Acres Treated	Pounds ai Handled
A1	Citrus	5.0	3.0	15
	Peach	3.0	5.0	
A2	Citrus	5.0	6.0	30
	Peach	3.0	10.0	
A3	Citrus	5.0	8.0	40
	Peach	3.0	13.3	
A4	Citrus	5.0	10.0	50
	Peach	3.0	16.7	
A5	Pecan	5.0	12.0	60
A6	Pecan	5.0	13.0	65
A7	Pecan	5.0	16.0	80
A8	Pecan	5.0	16.0	80

The clothing to be worn by the volunteers will consist of long sleeved shirts and long pants, shoes plus socks, and chemical-resistant gloves in accordance with the Worker Protection Standard (WPS). Volunteers may wear their own clothing provided they are freshly laundered (otherwise the AHETF will provide freshly laundered clothing). Any personal protective equipment (PPE) that is also required, such as gloves, will be provided by the study director.

Dermal exposure measurements will employ long cotton underwear (a surrogate for skin) worn under the volunteers single layer of clothing (long sleeved shirt and long pants), hand rinses and face/neck wipes. The face and wipe solutions will consist of 0.01% Aerosol OT solution. OSHA Versatile Samplers (OVS) outfitted with glass filters, XAD-2 sorbent, and tygon tubes will be used to measure inhalation exposure. The pumps will be calibrated at a rate of 2L/minute. The tubes will be attached to the volunteer's collars with the openings positioned in their breathing zones.

After monitoring, the dosimetry will be collected in the following order: inhalation, hand rinses, face and neck wipes and finally the inner dosimeters (with outer clothing being removed by the individuals privately). The inner dosimeters for mixer/loaders and open cab applicators will be cut into six sections representing the upper and lower arms, the front and back torso and the upper lower legs. For closed cab/cockpit applicators, the inner dosimeters will be divided into two sections, upper and lower body.

Hand rinses will be collected using 0.01% Aerosol OT. Hands will be washed prior to monitoring. Rinses will be collected at the end of the monitoring period with additional rinses being collected if a volunteer stops to eat, smoke or use the toilet. Likewise, the face and neck wipes will also use 0.01% Aerosol OT and collected with s gauze sponges with additional wipes being performed in a volunteer stops to eat, smoke or use the toilet.

On at least two study days, each dosimetry matrix will be fortified in triplicate at the following levels (µg/sample). Decisions to conduct additional fortifications on additional days are left to the discretion of the study director.

Matrix	Level (µg/sample)
Inner Dosimeter	5, 100, 5000
Face and Neck Wipes	5. 100, 2500
Hand Rinses	5, 100, 5000
OVS	0.05, 1.0, 50

The fortified samples will be exposed to the field conditions at a nearby location upwind of the mixer/loader or application operations. The inner dosimeters will be covered with shirt material and be exposed to the same conditions as the measurement dosimeters. Fortified air samples will be operated in a similar manner as worn by the volunteers. The hand wash and face/neck wipes will be fortified and be placed directly into storage.

On each field fortification day, duplicate samples of the inner dosimeters fortified at the highest fortification level will be processed for immediate frozen storage and serve as travel spikes. Duplicate OVS tubes fortified at the highest fortification level will serve as a travel spike. In addition there will be two untreated controls for the inner dosimeter and OVS matrices. However, the controls will be handled in the manner of the field fortifications.

In addition to the results of the analysis of the dosimetry and field fortifications, the following records will also be provided in the study report:

- Test substance (reference and control number)
- Crop description and stage of growth
- Mixing/loading and or application details, observations and equipment type
- Application maintenance records
- Environmental conditions (portable weather station data or nearest NOAA recording site
- Personal details of the workers (including consent forms)
- Location and site map, dimensions of plots
- Pounds active ingredient handled per replicate
- Dermal exposure sample information
- Inhalation exposure sample information
- Field observations (including photographs)
- Sample information (including chain of custody).

The Agency believes that this study, if appropriately conducted, will provide critical information related to the exposures that would be expected for individuals who apply liquid sprays of agricultural pesticides with airblast equipment using closed cab tractors. It is also believed that the monitoring techniques proposed for this study represent the current state-of-the-art. However, the Agency also recognizes that use of the data resulting from this study will also take careful scrutiny and may require a number of adjustments depending upon the results. Finally, the overall design of this study should be considered in the context of the goals of the AHETF which are to develop a broad-based database that can be generically used as a predictive tool for estimating exposures to pesticide handlers and that the interpretation of the results of this study may or may not necessitate the need for additional monitoring data for the airblast application of liquid sprays with open or closed cab tractors.

COMPLIANCE:

Study Conduct: This study will be conducted in compliance with the U.S. EPA FIFRA Good Laboratory Practice (GLP) Standards (40CFR160) and will adhere to applicable AHETF and/or field facility standard operating procedures (SOPs). Both the field and analytical phases of this study will be audited as well as the generation of the final report by the independent Quality Assurance Unit for the investigators as required by the GLPs with findings being available for review in the final study report. Any protocol amendments or deviations will be included in the final report as well as an assessment of their overall impact on the results of the study.

[See http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=794275183132+39+0+0&WAISaction=retrieve]

Ethics & Informed Consent: The Agency's review of the ethical components of this study is included in a separate document for consideration by the HSRB (i.e., see John Carley memo, 2006). This protocol was reviewed by the Western Institutional Review Board (WIRB), Olympia Washington. A series of documents produced by the either the AHETF or the WIRB pertaining to this study are included as Appendix A as background information for the HSRB to consider in its deliberations. These include: WIRB submission requirements and other administrative correspondence; a WIRB approved informed consent form (along with working drafts and WIRB required edits); an emergency hospitalization procedure for subjects; a WIRB *"Certificate of Approval"* for this study; and a list of the WIRB panel members. [See http://www.wirb.com/]

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GUIDELINE OR PROTOCOL FOLLOWED:

The protocol for this study is based on a design that was developed by the AHETF after joint discussions with the United States Environmental Protection Agency, Health Canada, and the California Department of Pesticide Regulation. This protocol was specifically developed in the context of the overall research plan for AHETF where the effect of different parameters on exposure levels will be evaluated based on these and other similar data that will be used to populate a database which will be used for analysis purposes.

The basic elements of the protocol are described in the following Agency guidance documents including:

- U.S. Environmental Protection Agency, Occupational and Residential Exposure Test Guidelines, Series 875.1000 through 875.1600. (1996) The guidelines are available at the following:

  http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/875_Occupational_and_Residential_Exposure_Test_Guidelines/Series/

- U.S. Environmental Protection Agency, Working Draft - Occupational and Residential Exposure Test Guidelines, Series 875 Group-B, Postapplication Exposure Monitoring Test Guidelines Version 5.4 (1998) The working draft guidelines are available at:

  http://www.epa.gov/scipoly/sap/1998/march/contents.htm

The initial protocol design for this study was developed based on the guideline documents referenced above. However, the design of this study has been considered in the context of the goals of the AHETF to compile information across many studies in order to evaluate how factors can impact exposures.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material: Sevin ® Brand XLR Plus Carbaryl Insecticide
EPA Registration Numbers: 264-3333
Lot & Container Descriptions: To be recorded at field site.
Common Chemical Name Of Active Ingredient: carbaryl
CAS Number of Active Ingredient: 63-25-2
Nominal concentration of active ingredient: 4 lb ai/gallon

2. Relevance of Test Material to Proposed Formulation(s):

The use of a carbaryl (Sevin XLR) formulation for the purposes of this study is considered appropriate. The intent of the AHETF is to develop a series of data that can be used to generically predict handler exposure levels. In order to accomplish this in a systematic fashion and to alleviate the potential for confounding results that may be caused by analytical methodology issues the AHETF selected a limited number of chemical active ingredients for use in their research program. These ingredients, including carbaryl, tend to have broad use patterns across agriculture in order to allow for the evaluation of exposures in many different settings which are included in the research plan for AHETF (i.e., end-use product labels for these chemicals allowed use on many crops and using many types of equipment). These chemicals also have analytical methods for the monitors which are to be used in this study that provide for reproducible results in a reliable manner and that have appropriately low screening levels.

3. Packaging:

The protocol indicated that open-pouring of a liquid product will be evaluated in this study. The size of the particular containers (e.g., jugs) was not indicated but the package sizes are to be recorded by the field investigators. [Note: Exposures of applicators would not be expected to be affected by the nature of the packaging because the applicator monitoring to be completed in this study only will evaluate exposures associated with application of an already prepared liquid spray solution.]

B. STUDY DESIGN

The overall AHETF research plan is to evaluate exposures for occupational pesticide handlers in agricultural settings using a wide array of mixing/loading and application equipment and using different types of personal protective clothing/equipment in order to develop an exposure database that can be generically used by stakeholders to predict exposures for occupational pesticide handlers.

The primary goal of this study is to address an element of the overall goal by quantifying exposures for those involved in the airblast application of liquid spray solutions to orchard crops in Georgia or Florida with closed cab tractors. A secondary goal, should an appropriate field situation arise, is to also quantify the exposures of mixer/loaders with liquid products and open pouring techniques in preparation for typical agricultural applications of pesticides.

Critical elements of the proposed study are described below and include (1) the numbers and types of workers/sites to be monitored; (2) the level of personal and protective clothing/equipment to be used by the monitored subjects; (3) a description of the mixing/loading equipment and application equipment to be used; (4) a description of the application rate to be used; (5) a description of the exposure monitoring methods to be used; (6) a description of the analytical methodology; (7) a summary of the analytical quality control elements contained in the proposed study; and (8) the relevancy of the proposed monitoring is discussed related to current agricultural practices and the available data that can currently be used to assess these uses.

1. Number and type of workers and sites:

In Section 5 (page 13 of 32) of the protocol, it is indicated that "up to 8 different applicator workers (or replicates) will be monitored for exposure" based on the following suggested scheme:

Replicate No.	Crop	Rate (lb ai/acre)	Acres Treated	Pounds ai Handled
A1	Citrus	5.0	3.0	15
	Peach	3.0	5.0	
A2	Citrus	5.0	6.0	30
	Peach	3.0	10.0	
A3	Citrus	5.0	8.0	40
	Peach	3.0	13.3	
A4	Citrus	5.0	10.0	50
	Peach	3.0	16.7	
A5	Pecan	5.0	12.0	60
A6	Pecan	5.0	13.0	65
A7	Pecan	5.0	16.0	80
A8	Pecan	5.0	16.0	80

As also indicated above, mixing/loading events may also be monitored at the discretion of the Study Director (i.e., the total number of possible events was not specified). It is optimal that each "replicate" be a unique individual. [Note: In Section 3 (page 7 of 32) the protocol indicates that the "number of workers monitored will be determined based on available resources in the field and will be detailed in the raw data." It is also important to consider the number of monitored workers in the context of the overall AHETF database development goals.]

In Section 3 (page 7 of 32) it is indicated that "all monitored workers will be professional agricultural workers who will be required to give their informed consent to participate in the study. Section 5.3 (page 8 of 32) provides additional information pertaining to the workers to be monitored in this study. This section indicated:

> "Adult workers will be selected who are experienced in the work activities under study and who consider themselves to be in good health. In particular, the mixer/loader workers will have experience with the specific closed system being used. They should also have a willingness to cooperate in a study of this type and have no conflict of interest in the conduct or outcome of the study. The reproductive status of all potential female participants will be ascertained through the use of a supervised urine pregnancy test conducted within 24 hours prior to initiation of monitoring. Any pregnant subjects will be excluded from the study due to the potential stress from wearing the dosimeters. The volunteers will be at least 18 years of age.
>
> A signed informed consent form will be obtained from each worker prior to their participation in the study. This protocol, as well as the informed consent form and worker selection process, will be reviewed and approved by an Institutional Review Board (IRB) prior to worker exposure monitoring. [Note: See Appendix A for further information.]
>
> Each worker will be provided with a full explanation of the study, its requirements, and any potential risks. Workers will be advised of their right to withdraw from the study at any time and for any reason without jeopardizing their normal position with their employers. In order to maintain confidentiality in their final report, only the unique worker identity number will identify each worker.
>
> Personal details including name, age, gender, body weight, height, previous experience in the work activity, and a general health statement, as provided by the worker,will be maintained in the study file. Workers will be asked to bathe or shower prior to each day of monitoring to minimize any possible contamination from one day to the next and from any outside pesticide sources."

The field locations will be three or more sites in southern Georgia or Florida. Field maps and other data will be collected to document the site and equipment used for each monitoring event. In Section 5.9 (page 12 of 32) it was indicated " the exact configuration and size of equipment will be dictated by what is available in the field; however, the study director will make an attempt to utilize a variety of standard equipment throughout the study."

2. Protective clothing & Equipment:

The workers will wear normal work clothing with whole-body dosimeters underneath. Normal work clothing will be "WPS compliant" [i.e., Worker Protection Standard] according to the protocol and will consist of long-pants and long-sleeved shirts. These garments will be either "freshly laundered or new and free from pesticide residues" based on a worker self certification process. Shoes and socks will also be required. According to the carbaryl labels, waterproof gloves are also required and shall be worn by each monitored subject. [Note: Per WPS criteria, it would not be expected that applicators would were gloves while inside of a closed cab.]

Applicators will be monitored using airblast sprayers (i..e, a common application method on orchard crops such as pecans, citrus or peaches) with closed-cab tractors (i.e., closed-cabs offer more protection and are considered an engineering control, hence, under WPS gloves and protective eyewear can be removed while in the cab). If mixer/loader exposures are monitored, open-pour loading of liquids (i.e., Sevin XLR) will be evaluated in this study.

3. Mixing/loading/application method:

As indicated above, the primary purpose of this study is to monitor workers who will apply already prepared spray solutions of carbaryl using airblast sprayers and closed-cab tractors depending upon what is available in the field (e.g., http://johnbeansprayers.durand-wayland.com/series/redline/redline600c.html). The target duration for each monitored interval will be 4 hours. According to the protocol (Section 5.7, page 10 of 32) if mixing/loading is monitored it will be with an open-pour system (e.g., probably jugs)

The accuracy of the equipment used will be verified prior to use in the study including equipment used to weigh, pump, or meter test substance and carrier (i.e., water).

4. Application Rate:

As indicated above in Section B.1 the intent is to monitor subjects for approximately 4 hours who handle in the range of 15 to 80 pounds of active ingredient during the monitoring event.

The target application rate, according to the protocol in Section 5.7 (page 10 of 32), will depend "on crop and field needs; 5 lb ai/acre for pecan and citrus, 3 lb ai/acre for peach Application rates will be documented in the study raw data."

Application volumes will also "depend on equipment, but application volumes will generally range from 100 to 300 gallons/acre."

5. Exposure monitoring methodology:

Pesticide exposure predominantly occurs to the skin with smaller amounts (e.g., typically 5 percent or less of the total) occurring as inhalation exposure. There are essentially two basic techniques for quantifying exposures to pesticide chemicals: biological monitoring or passive-dosimetry. Each technique has negative and positive attributes associated with it as described in the guideline documents referenced above. The AHETF has opted to use a passive dosimetry approach, which is the more common monitoring method. The passive dosimetry techniques which are to be utilized by AHETF in the completion of this study are the most commonly employed approaches for completing occupational monitoring studies.

Dermal exposure sampling typically includes defining the amount of residues that could potentially be deposited on the skin of a monitored individual. To adequately quantify dermal exposures for the entire body, three different monitoring approaches are to be used in this study including whole-body dosimetry which will cover skin areas from the neckline to wrists and feet. A wiping technique will be used to collect residues from the face and neck area and a washing technique will be used to collect residues from the hands. Full details of the processes and procedures to be used for dermal sampling are included in the standard operating procedures (AHETF SOPs 8.A; 8.B; 8.C; 8.D; 8.H; and 10.E) which are available for review. Separate procedures are also available that pertain to inhalation sampling (AHETF SOPs 8.D & 10.A).

A brief summary of the techniques to be used for both dermal (all types) and inhalation sampling is provided below.

Dermal Using Whole-Body Dosimeter: As indicated above in ***Section 2 – Protective Clothing*** and AHETF SOP 8.A, normal work clothing will be worn over top of the whole-body dosimeter. The intent of the whole-body dosimeter is to capture residues that could deposit on the surface of the skin which in turn could be available for absorption through the skin resulting in a dose. The dosimeter "will consist of 100 percent white cotton long underwear provided by the AHETF. The inner dosimeter is designed to represent the worker's skin and will act as a collection medium that will be analyzed. It will be worn throughout the period of monitoring and will be removed at the end of the work period. At the end of the monitoring period (and after the inhalation exposure equipment are removed), the worker will first remove his/her gloves and shoes, and then enter a clean, private area for collecting the remaining samples. Once inside the private area, the worker will remove his/her outer clothing and socks. The outer layer of clothing will not be collected or analyzed." Once removed, "the inner layer of clothing (inner dosimeter) will be removed with the assistance of a member of the study team and sectioned into upper and lower arms; front and back torso; and upper and lower legs." Samples will be wrapped in aluminium foil then stored frozen in pre-labelled containers.

Dermal Face and Neck: As indicated in AHETF SOP 8.C, a wipe technique will be used to quantify exposure levels to the face and neck area. This will be accomplished by "wiping the entire face and neck areas (front and back) with two gauze sponges, sequentially, that have been wetted with 0.01 percent Aerosol OT" which is a mild aqueous soap solution. If workers stop to eat during the monitoring period, wipe samples will be collected. Workers will be asked to wash their face or wipes will be used before the monitoring period begins to clean their faces so that only residues which are deposited during the monitoring period will be collected. Like the whole-body dosimeters, samples will be wrapped in aluminium foil then stored frozen in pre-labelled containers.

Dermal Hand: As indicated in AHETF SOP 8.B, a washing technique will be used to quantify exposure levels to the hands (i.e., the amount of residues deposited on the hands). This will be accomplished by "having the worker wash their hands in a 0.01 percent Aerosol OT solution according to a standardized washing procedure" as described in the SOP. Workers will be asked to wash their hands before the monitoring period begins to clean their faces so that only residues which are deposited during the monitoring period will be collected. Handwash samples will be collected from workers "whenever a worker would normally wash his/her hands (e.g., before using the toilet, before using tobacco, etc.).." Samples will also be collected at the end of the monitoring period. All handwash samples will be kept separate and individually labelled and will be stored frozen in pre-labelled containers.

Inhalation: As indicated in AHETF SOPs 8.D & 10.A, a personal air pump coupled with an OVS (OSHA Versatile Sampler) tube (e.g., http://www.msanorthamerica.com/catalog/product685.html & http://www.skcinc.com/prod/226-30-16.asp) will be used to monitor inhalation exposure levels. The OVS tube will contain a glass fiber filter and XAD-2 sorbent. Pumps will be calibrated to a flow rate of 2 Lpm before and after sampling. Pumps will be attached to the workers' belts and the OVS sample tube (attached via tubing to the pump) will be located on the workers' collars in their breathing zones to capture representative air samples of concern. Like with the other sampling devices described above, OVS samplers will be collected at the end of each monitoring period and stored frozen and individually labelled.

It should be noted that these monitoring techniques are very commonly used for the monitoring of occupational exposures to pesticides. The use of these techniques does not preclude adjustments to the resulting data based on a variety of possible factors that could account for such phenomena as losses during sampling of collected residues, possible incomplete residue collection (e.g., from hands) and other factors such as breakthrough or volatility losses from OVS samplers which could be determined in the analysis of these data.

6. Analytical Methodology:

For each of the sampling media in this study (i.e., whole-body dosimeters, handwash, face/neck wipes, and OVS tubes) there is a separate analytical method which has been developed in order to quantify the levels of carbaryl residues contained in that media. In addition to the sampling media, representative lots of the carbaryl (Sevin XLR) formulation and the spray solutions will be collected and analyzed to verify the levels of carbaryl in the materials handled/prepared by the monitored subjects.

The specific analytical methods to be used in this study are referenced below (and have been provided separately for review purposes):

- Analytical Method No. ARTF-AM-011: Determination Of Carbaryl In Dermal Dosimeters, Rev. 3 by Gary Westberg, 1998;
- Analytical Method No. ARTF-AM-012: Determination Of Carbaryl In Hand Exposure Samples, Rev. 1 by Gary Westberg, 2001;
- Analytical Method No. ARTF-AM-013: Determination Of Carbaryl In OVS Air Sampling Tubes by Gary Westberg, 1997; and
- Analytical Method No. ARTF-AM-014: Determination Of Carbaryl In Cotton Facial/Neck Wipes by Gary Westberg, 2000.

The methods used for carbaryl on each of the sampling media used for this study have been evaluated and are applied generically within the scenarios to be evaluated by the AHETF where carbaryl may be used to estimate exposures for several occupational handler tasks. The screening limits established for these methods have been deemed appropriate for these types of studies. Substitutions of equivalent instrumentation, reagents, or other materiel are allowable. Procedural changes require study director approval. All data will be calculated against a standard curve with a limit of determination (r^2) $\geq$ 0.90 or regression coefficient (r) $\geq$ 0.94.

All manner of records will be maintained in accordance with FIFRA Good Laboratory Practice requirements and will include (but not necessarily be limited to) worksheets, notebooks, chain-of-custody records, chromatograms. Instrument log and maintenance books, substance use logs and archival samples of the analytical materials used will also be retained.

7. Quality Control:

The proposed study incorporates several quality control elements into its overall design. The first is that extensive records will be kept that pertain to the design, conduct of the study in the field, conduct of the study in the analytical laboratory, and the reporting phase. Additionally, independent quality assurance unit will audit each critical phase of the study and report to the sponsor organization any items of note as specified in the FIFRA Good Laboratory Practices.

Field records will document a variety of elements of the study including the chemicals used, the cultural practices in which the monitored subjects are involved, any equipment used by the subjects in the study, the exposure monitoring methods, and any data related to the nature of the site that is important (e.g., sample storage conditions). Photographic and video records will also be collected and maintained to aid in the interpretation of the results of this study (e.g., video records of subjects engaged in various monitored activities). Calibration of appropriate equipment will also occur and may include flow rates for personal sampling pumps, flow meters for adding water when preparing spray solutions, scales/balances for preparing analytical solutions and spray solutions, and spraying systems (e.g., airblast sprayer and tractor) when applications are monitored in this study. Logs that track chemical usage will also be maintained in order to ensure proper preparation of test solutions and to document the use of appropriate chemicals during the conduct of the study.

In addition to the procedures outlined above and elsewhere in the protocol, a number of control samples (both positive and negative) will be generated and analyzed in order to ensure the overall viability of the analytical phase of this study and also to allow for the derivation of appropriate residue adjustment factors which can be used to account for the loss of residues from field monitors during the monitoring periods themselves, during sample transport/storage, possible contamination of field monitors, and from analytical methods which do not quantitatively evaluate residues (i.e., are only capable of capturing a certain percentage of the available residues). These can be categorized in the following manner:

Prefield Testing & Method Performance Evaluations: These types of samples are intended to evaluate the overall ability of the analytical method to extract and quantify the residue of interest (in this case carbaryl) from the various media used for sampling (e.g., cotton whole-body dosimeter shirts). These evaluations are commonly referred to as method validation. Additionally, it is important to also ascertain how much possible residue loss from a sampler might occur under field conditions (e.g., OVS tube after air has been pulled though it) in order to anticipate the performance of the method while monitoring under actual field conditions. This work has already been completed and will be documented for each media in the analytical methods referenced above.

Laboratory Recovery: During the analysis of samples in the laboratory, it is important ensure that the analytical method is performing appropriately (e.g., instruments are working and processes are appropriately completed). In order to do this both positive and negative control samples are analyzed with each batch of field samples to ensure that no adverse levels of unwanted contamination are present (i.e., negative controls) and that the analytical method is functioning properly within given performance criteria (i.e., positive controls). A minimum of "two laboratory spikes must be included in each analytical set." For larger sets of samples, a positive control sample is to be included for every 10 field samples. Positive control samples will be fortified at levels expected to bracket the levels anticipated in the field samples.

Field Recovery: As with the laboratory recovery samples above, both negative and positive control samples will be generated. Negative control samples will be used to evaluate the possibility for sample contamination throughout the sample handling and storage process prior to analysis. The positive control samples are intended to evaluate "the stability of the active ingredient [in this case, carbaryl] under field, storage, and transit conditions in or on the sampling materials (inner dosimeters, handwash solutions, face/neck wipes, head patches, and air sampling matrices)." Field recovery procedures will be completed as described in AHETF SOP 8.E.

On at least two study days, each dosimetry matrix will be fortified in triplicate at the following levels (µg/sample). Decisions to conduct additional fortifications on additional days are left to the discretion of the study director.

Matrix	Level (µg/sample)
Inner Dosimeter	5, 100, 5000
Face and Neck Wipes	5. 100, 2500
Hand Rinses	5, 100, 5000
OVS	0.05, 1.0, 50

The fortified samples will be exposed to the field conditions at a nearby location upwind of the mixer/loader or application operations. The inner dosimeters will be covered with shirt material and be exposed to the same conditions as the measurement dosimeters. Fortified air samples will be operated in a similar manner as worn by the monitored subjects (i.e., air drawn through at 2 Lpm for the duration of the monitoring period). The hand wash and face/neck wipes will be fortified and be placed directly into storage which is what would occur during actual sampling since they would be done at the end of a monitoring period.

Positive control field recovery samples can evaluate sampling media residue losses from the point of field monitoring inception through field storage, shipment, and analysis. In many cases, the most significant losses occur from the sampling media during actual field monitoring because they can last for hours and typically occur under field conditions that are conducive to residue losses (i.e., hot and humid weather). To better characterize where potential losses may occur in the sample collection through analysis timelines, AHETF is also proposing the generation of "travel spikes" will occur to evaluate losses solely due to storage and shipment because they are not exposed to field conditions as they are packaged and freezer storage immediately after dosing. If analyzed, these will provide additional information to help characterize where in the lifetime of the collected samples where residue losses possibly occurred.

8. Relevancy of Study to Proposed Use:

In order to achieve proper foliage coverage with the applications of certain pesticides to orchard crops (which is needed for efficacy purposes), airblast sprayers need to be used because they push droplets into the tree canopy by creating a slipstream of air across a bank of spray nozzles (e.g., http://johnbeansprayers.durand-wayland.com/series/redline/redline600c.html). These devices are typically mounted on independent trailers where the major components are a spray tank (e.g., 500 gallons), a nozzle bank, a power source (i.e., tractor PTO or motor to self power), and a large fan. The use of these devices is very common for applications to tree fruit and nut crops; in fact it is the predominant method for tree crops. For other crops, mainly those using trellises as part of the agronomic practice, airblast sprayers are also used.

The Agency uses a scenario-based approach for completing occupational exposure/risk assessments. This process involves defining the crops upon which a pesticide can be applied and then ascertaining what types of equipment is used to treat those crops. Based on what is known about the culture of tree fruits and nuts and trellis crops, it is clear that the use of airblast sprayers for application to tree crops is an exposure scenario of interest as is application to trellis crops. The Agency currently has values which can be used to estimate exposures for these scenarios. However, the values currently in use represent cultural practices from approximately 20 years or so ago. Additionally, with this proposed new study the Agency is interested in better understanding exposures with modern equipment and practices; quantifying exposures using whole-body dosimetry (instead of the older patch monitoring method – see guideline documents for further information); and completing a better evaluation of the impact on exposure of the amounts handled because these data will be used in a generic sense.

Given this backdrop, the Agency believes that there is a need for updated monitoring data with which to predict exposures for occupational mixer/loaders using closed systems and liquid products. The Agency believes that the proposed data will provide information that is more relevant to the systems that are more typical in modern agriculture. Thus, it follows that the exposure values predicted using such data would also be more representative of modern agricultural practices.

The following summarizes some of the key issues related to the representativeness of the proposed study.

Element	Applicability/Comments
Active ingredient	A Carbaryl (Sevin XLR) formulation is to be used in this study. Carbaryl and its associated use practices as representative of chemicals widely used in agriculture.
Formulation	A 4lb ai/gallon XLR formulation (i.e., liquid suspension or flowable concentrate) is very typical of many of the liquid formulations widely used in agriculture.
Packaging	The packaging sizes proposed for this study were not specified but are to be commercially available
Max. application rate	The unit exposure estimates to be generated from this study are exposures normalized by the amount of active ingredient handled and these values are to be used generically. As such, achieving the maximum rate is not critical. It is important, however, that sufficient quantities of material be used to achieve measurable results. It does appear to be the case with this study given that analytical screening limits are very low.
Total ai handled	The range of proposed amounts of total active ingredient handled appear reasonable and the range represents a likely range to be anticipated in agricultural settings.
Mixing/loading method	The proposed systems appear appropriate given the state of current agricultural practices.
Application equipment	The proposed systems appear appropriate given the state of current agricultural practices.
Clean-up, repair, etc.	The proposed systems appear appropriate given the state of current agricultural practices.
Protective clothing	The proposed levels appear appropriate given the current carbaryl labels.

II. RESULTS AND CALCULATIONS:

The manner in which the results are summarized will depend upon the nature of the situations that are monitored (e.g., types of equipment, clothing & personal protective equipment used), the quality control results and the exposure values that are identified. The ultimate goal is to provide summary exposures for the types of scenarios that have been monitored. Pesticide handler exposures are typically presented on a unit basis and the most commonly used is amount of exposure per pound of active ingredient handled (i.e., µg/lb active ingredient handled). For example, if both mixing/loading and application are monitored in this study, then a different unit exposure for each activity would be calculated. As appropriate, different statistical values will also be defined (e.g., mean, median, percentiles of exposure).

III DISCUSSION

A. LIMITATIONS OF THE STUDY:

At this point, and given the context of how this study will be used in relation to the overall goals of the AHETF to create a generic database for generically predict pesticide handler exposures, the Agency does not believe that this protocol has serious technical limitations. Defining all possible limitations associated with the proposed monitoring of occupational pesticide mixer/loaders during the preparation and application of varying amounts of carbaryl spray solution is indeterminate at this time because the results and associated limitations of the study will greatly depend upon the situations which are identified and monitored by the field investigators. They will also depend on the performance of the analytical methods and how samples are collected and handled in the field. From a design perspective, this study represents the current state-of-the-art approach for conducting a passive-dosimetry based monitoring study.

It should be noted, however, that the use of the data generated in this study by the U.S. EPA and other stakeholders will depend upon the nature of the results. For example, the adequacy of the field or laboratory recovery data may dictate that correction factors are applied to adjust monitored exposure levels to account for losses from field samplers or low performing analytical methods. Additionally, other factors may be possibly employed related to the use of the data from this study. For example, the proposed handwash technique that is to be used to measure hand exposures is under scrutiny and a factor could be used by the Agency to adjust for incomplete collection of residues from the hands if this is deemed appropriate.

B. CONCLUSIONS:

The Agency believes that this study, if appropriately conducted, will provide critical information related to the exposures that would be expected for individuals who apply liquid sprays of agricultural pesticides with airblast equipment using closed cab tractors. It is also believed that the monitoring techniques proposed for this study represent the current state-of-the-art. However, the Agency also recognizes that use of the data resulting from this study will also take careful scrutiny and may require a number of adjustments depending upon the results. Finally, the overall design of this study should be considered in the context of the goals of the AHETF which are to develop a broad-based database that can be generically used as a predictive tool for estimating exposures to pesticide handlers and that the interpretation of the results of this study may or may not necessitate the need for additional monitoring data for the airblast application of liquid sprays with closed cab tractors.

Appendix A
AHE38 Protocol Review
WIRB Documents