Summary: Agency Science Review Of Agricultural Handlers Exposure Task Force (AHETF) Protocols Prepared For EPA Human Studies Review Board (Protocols AHE-34, 36, 37, 38, & 42)

The Agricultural Handlers Exposure Task Force (AHETF) submitted 5 protocols for consideration by the Agency as part of their multi-year research program for addressing issues related to the calculation of occupational pesticide handler exposures. These proposed studies can be identified by the following citations:

- AHETF Study No. AHE34; Determination of Dermal and Inhalation Exposure to Workers During Closed System Mixing/Loading A Liquid Pesticide Product.
- AHETF Study No. AHE 36; Determination of Dermal and Inhalation Exposure to Workers in the West During Airblast Applications to Trellis Crops Using Open or Closed Cab Equipment.
- AHETF Study No. AHE 37; Determination of Dermal and Inhalation Exposure to Workers in the East During Airblast Applications to Trellis Crops Using Open or Closed Cab Equipment and During Open-Pour Mixing/Loading a Wettable Powder Pesticide Product.
- AHETF Study No. AHE 38; 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.
- AHETF Study No. AHE 42; Determination of Dermal and Inhalation Exposure to Workers in the Pacific Northwest During Aerial Applications to Crops Using Closed Cockpit Fixed-Wing Aircraft and During Open-Pour or Closed System Mixing/Loading of a Liquid Pesticide Product.

The AHETF is a multi-company task force that is comprised of various major pesticide registrants. The contact information for the AHETF is provided below:

Agricultural Handlers Exposure Task Force
c/o Stewart Agricultural Services
P.O. Box 509
Macon, MO 63552

EXECUTIVE SUMMARY:

These studies are 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 can be used generically by various stakeholders (e.g., applicants, registrants, EPA, and others) for calculating exposures for the occupational handlers of pesticides. The scope of the AHETF is very broad in that it intends to address exposures related to many job functions in agriculture and also to assess the impacts of various parameters on exposure (e.g., How do changes in the pounds of pesticide handled or acres treated impact exposure levels?). Given this context, these protocols define only the five studies cited above which are intended to measure exposures for the specific scenarios (i.e., job functions) for which they are intended (e.g., closed or open system mixing/loading , airblast applications to trellis and orchard crops, or pilot exposures from fixed wing agricultural aircraft).

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 assessment 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 than what are available at this point 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.

The primary objective of these studies is to collect as many replicates (i.e., an exposure monitoring event in which a set of sampling devices is collected generally representing exposures for at least 4 hours of work) as possible under actual field conditions within the specified limits of each protocol. The focus is to evaluate exposures for actual farmworkers using actual field equipment under a variety of field conditions so trends can be defined related to exposure changes. An example sampling regimen proposed for AHE-34 provided below illustrates this design approach. 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 and conduct of these studies.

Example Sampling Regimen From AHE-34 (Closed Loading Liquids)				
Replicate	Day	Container Size	Number of Containers	Pounds ai Mixed
M1	1	2.5	2	25
M2	1	2.5	7	125
M3	1	5	6	225
M4	2	30	2	325
M5	2	5	11	425
M6	2	55	2	525
M7	3	30	3	625
M8	3	55	2	725
M9	4	55	2	825
M10	4	55	3	925

The clothing to be worn by the monitored volunteers in all studies will consist of long sleeved shirts and long pants, shoes plus socks, in accordance with the EPA 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 required for the particular study (based on the pesticide labels or WPS requirements), such as chemical resistant gloves and protective eyewear, will be provided by the study director.

Exposure monitoring will be completed using standardized techniques generally referred to as passive dosimetry. 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), handwashes, and face/neck wipes. Hand exposures will be monitored using a washing technique with soapy solution and the face/neck wipes will be wetted with the same solution. Air samplers known as OSHA Versatile Samplers (filters with sorbent in a single device) will be used to measure inhalation exposure with air sampling pumps calibrated at a rate of 2L/minute.

Extensive quality control elements are required for studies of this nature. This includes several procedures for both the field and analytical phases of such studies. Field phase elements include such items as tracking of test substance inventories and calibration of field equipment (e.g., sprayers) and sampling equipment (e.g., air sampling pumps). The analytical phases of such studies also have extensive quality control elements associated with them designed to ensure the integrity of the results. This involves an extensive chain of custody process, laboratory controls (i.e., positive and negative) to ensure that analytical methods are functioning, and field controls (positive and negative) to evaluate to stability of collected residues on field samplers from the time of collection to analysis. These studies will also 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.

In addition to the results of the analysis of the collected samples, the following records will also be generated:

- 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 science elements of the proposed studies have been considered in conjunction with the ethical components of the proposed studies. The ethical review of the proposed protocols is included in a separate document for consideration by the HSRB (i.e., see John Carley memo, 2006). Each 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 these studies are included 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/]

The Agency believes that these studies, if appropriately conducted, will provide critical information related to the exposures that would be expected for individuals who mix and load or apply agricultural pesticides with equipment of various types. 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 these studies 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 to address lingering concerns about the scenarios included in these studies.

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.

[Note: Each protocol has been individually reviewed. The reviews and all supporting documentation are included in the HSRB package which has been prepared by the Agency.]