

## **Supplemental Materials in Response to EPA Follow-up Questions**

### **Work Assignment 4-06 of Battelle Contract EP-W-04-021 Review of AHETF Sampling Design Documentation**

**Warren Strauss and Louise Ryan**

**June 6, 2008**

On May 22<sup>nd</sup>, 2008 we provided EPA's Office of Pesticides Programs with a review of the AHETF Sampling Design Documentation. The goal of our review was to determine whether the Governing Document and subsequent documentation on the pending Closed-Cab Airblast Field Studies were reasonable, sufficient, and based on sound statistical principles. Our initial review identified areas of strength and weakness in these documents, and provided recommendations on an alternative design that might be considered for the Closed-Cab Airblast Field Studies, as well as some strategies that could be employed to add rigor and statistical/scientific defensibility to the field study plans. During a follow-up telephone call, technical staff from EPA provided additional information relative to their objectives for data quality from these field studies; and sensitivities that EPA and AHETF might have about the costs associated with implementing some of the recommendations that we made, including the alternative design which potentially doubled the number of locations that AHETF would need to use for the Closed-Cab Airblast experiment. On June 3<sup>rd</sup>, 2008 EPA provided a letter (attached as Appendix A) requesting some additional input following our initial review. This brief letter report provides some additional thoughts as a response to EPA's request for supplemental review and comment.

Our initial review was focused on whether the governing document, and subsequent test plan for the Closed Cab Airblast Field Study would provide adequate information for EPA to use for risk assessment purposes. Given the manner in which the Closed-Cab Airblast test plan utilized data from USDA in the number of bearing acres of different crop types that AHETF wanted represented within the field study – we initially thought that this information could potentially serve as the basis for conducting the first stage of sampling for a Nationally Representative Study. Such a design would lead to unbiased estimates of worker exposure across the U.S. – which would be ideal for EPA's risk assessment purposes. Based on our follow-up phone call with EPA, we now understand that there are additional assumptions that must be made to utilize the USDA information as a proper basis for a Nationally Representative Design. Specifically, EPA and AHETF do not know the fraction of bearing acres in each state that utilize Closed-Cab Airblast equipment to apply pesticides. It is entirely possible that these fractions are not uniform – which could certainly influence the representativeness of such a design. Thus, it is not clear whether AHETF could develop a proper (or pseudo) sampling frame to support a National Probability-Based Design.

In addition, we are aware of several studies that have been used to provide EPA with risk assessment information that have not initiated with a National Probability-Based Design. For example, EPA's National Human Exposure Assessment Study (NHEXAS) chose three different locations in the U.S. - Maryland, Arizona, and Region V (which includes IL, IN, MI, MN, OH and WI), and EPA's Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study investigated childhood exposures in Ohio and North Carolina. These studies have provided EPA with very reliable information on human exposure, without the necessity of a National Probability-Based Design.

We would like to note, however, that these studies (NHEXAS and CTEPP) followed a representative probability-based design within those geographic areas selected. This ensured that EPA could confidently state that their risk assessment estimates are unbiased and representative of those geographic areas that were selected as locations for the study. Thus, we think that it is certainly feasible for AHETF to select one or more large geographic areas (e.g., states) to perform their exposure studies – provided that they make a strong attempt to implement the study within those selected locations in a manner consistent with a probability-based design.

Within the context of the Closed-Cab Airblast design, this suggests that AHETF could select a single state to represent each crop type (as currently planned) – and then design a proper representative field study within each of those states. The desire to ensure representation across a range of ‘amount of active ingredient handled’ can be accomplished using stratification as discussed in our original review. We do not believe that conducting the field study in this manner would adversely affect the costs of implementation, and also believe that this added rigor will allow AHETF and EPA to construct unbiased and reliable exposure profiles that are at least representative of those states selected in the first stage of the design.

We still believe that both EPA and AHETF would benefit from selecting more than one location per crop-type in the Closed-Cab Airblast field study – allowing a State such as California to be represented in the study across multiple crop types (proportional to its high amount of agricultural production) while also introducing potential regional diversity into the study. However, we also recognize that this plan would increase the complexity and cost of implementation and may not be feasible within the AHETF’s resource constraints.

## **Appendix A**

### **Follow-up Questions Posed by EPA Office of Pesticides Programs**

In our teleconference on May 23, 2008 EPA/OPP staff discussed with you your comments on the sampling strategy described in proposed research submitted by the Agricultural Handler Exposure Task Force (AHETF). As we explained, EPA's goal for the AHETF-sponsored data collection effort is to obtain a new generation of monitoring data that better describes the diversity of conditions and exposures for agricultural pesticide handling scenarios – in a way that would produce a distribution that does not underestimate middle and upper-end exposures. The discussion focused mainly on the following EPA concerns relating to a probability-based design:

- The lack of an accurate sampling frame,
- The inability to obtain information to evaluate potential bias resulting from non-respondents, and
- The significant cost (estimated to be about \$100K) for each additional monitoring site beyond the 5 proposed by the AHETF

We agree with many of your observations about the AHETF materials. In view of the points above, however, we also have some concern about the feasibility and necessity of your suggested alternatives. Would you please take another look at your comments in light of these points, and determine whether your review should be revised or supplemented based on the additional information that that we conveyed during our conversation? We would like to be able to provide your final report to the HSRB at least a week before the scheduled beginning of their meeting on June 24.

In addition to the points summarized above, we would like to emphasize two additional concerns:

- First, EPA needs to be able to estimate future occupational exposure for pesticides given a proposed use pattern—e.g., a fungicide proposed for use on apples using airblast equipment. To predict exposure, pesticide handler exposure data has historically been expressed as units of exposure per amount of active ingredient handled (AaiH)—a normalization that assumes direct proportionality between exposure and amount handled. While the relationship between exposure and AaiH may not be directly proportional in all circumstances and scenarios, EPA expects to see proportionality in most cases, and to be able to use it to reasonably and simply predict future exposures associated with most scenarios.
- Second, EPA's review of available exposure data for pesticide handlers shows that exposure normalized by AaiH can generally be described by a lognormal distribution (i.e., skewed with a long tail to the right). When such a distribution is sliced into diverse strata as proposed by the AHETF, the sampling process will tend to oversample exposures from the tail of the distribution—i.e, from the high end—resulting in estimates of high-end exposure percentiles which are biased high (i.e., which will systematically exceed the corresponding true high-end percentile exposures in the population). This is why we believe the results of the proposed monitoring by AHETF will not underestimate the upper end of the distribution of exposures.

The AHETF program design was developed with these two concerns in mind. Since the Agency's primary objective is to characterize the lognormal distribution of normalized exposure with confidence that it does not underestimate the middle and upper end of the distribution, and since we think that goal would be met by the diversity selection design proposed by the AHETF, we find the proposed design acceptable in this respect.

In conclusion, EPA wants to arrive at a scientifically defensible sampling design for this research that will meet the Agency's needs and which can be executed at reasonable cost. Our immediate concern is to identify changes in the protocol associated with the design of the closed-cab airblast scenario that would improve the statistical defensibility of the design without significantly increasing the cost of the research, and that could be implemented quickly enough to allow the initiation of field monitoring in the summer of 2008.

Will the proposed purposive selection design incorporating random selection of growers from a purposively chosen section of a state address our goals? How could the proposed design be feasibly modified to better address EPA's goals?