SUMMARY OF EPA/OPP TELECONFERENCES WITH AHETF

On Wednesday, November 7, 2007, the Agricultural Handlers Exposure Task Force (AHETF) was a party to two teleconferences with staff of the US EPA. In the first teleconference, AHETF member company representatives joined in a meeting of the Antimicrobial Exposure Assessment Task Force (AEATF) in which EPA staff participated, including Bill Jordan, John Carley, Timothy Leighton, Cassi Walls, and Paul Lewis. In the second teleconference, EPA staff members joined in a meeting of the AHETF. EPA staff members who participated in the latter discussion included Bill Jordan, John Carley, Jack Housenger, David Miller, Phillip Villanueva, James Nguyen, Jeff Dawson, and Jeff Evans.

The discussions were the result of requests from the AEATF and AHETF for a series of actions on the part of EPA in regard to pesticide handler exposure data development programs planned by the two Task Forces. The following is a summary of the major points made by EPA representatives, presented primarily by Bill Jordan, during both teleconferences. Bill Jordan characterized the Agency's responses to the requests of the Task Forces as having been developed after discussions with and with the support of senior EPA management.

1. EPA has decided that it wants the data AEATF and AHETF propose to develop because the data should provide a better basis for assessing handlers' pesticide exposure than do currently available data.

2. EPA has determined that the range of scenarios described in the Governing Documents presented by the AEATF and AHETF are acceptable, but notes that some additional data may still be needed for scenarios outside the scope of the Task Forces' research.

3. Repeated measurements on the same individuals were recommended by the HSRB. EPA has determined that, these data are not needed. The number of feasible MUs is constrained by the Task Force's budget, and EPA believes it is more important to measure between-worker variability than within-worker variability. EPA can address the potential impact of within-worker variability on risk assessments analytically, using conservative assumptions to avoid underestimating potential exposure. EPA intends to present its decision to the HSRB at its next meeting.

4. EPA has decided that the proposed approach to determine the number of clusters and number of monitoring units (MUs) per cluster proposed by the AHETF and AEATF is acceptable. We understand that the AHETF will examine each scenario to determine whether existing data justify a different number of clusters and MUs, but in the absence of information the AHETF's research will default to a standard of 5 clusters of 5 MUs per cluster for each of its scenarios. Departures from this standard are possible when warranted by scenario-specific factors.

5. With the provisos stated below, EPA has determined that generation of handler exposure data using purposive diversity sampling (PDS) design is acceptable. EPA reached this position based on the following considerations: much time and resources have already been spent by the AHETF in developing an approach based on a PDS design, the delay and extra costs associated with developing a random sampling design approach would be significant, and the data developed

using a PDS design are anticipated to able to meet the scientific and regulatory needs of the Agency. The following provisos apply to this determination:

a. Full documentation of the methods and rationale for selection of locale, study site, crop, equipment, workers, etc., is included in each scenario-specific design document. Documentation should include relevant agricultural statistics and production figures, chemical sales/use data, and a description of the equipment to be used and a rationale for considering it to be representative for the scenario. All professional contacts who contributed information to the design process should also be identified, with a description of their position, expertise, and experience, and

b. Incorporation of random elements is considered in each scenario-specific design, and implemented whenever feasible. Cost estimates should be included for all alternatives considered, documenting the basis and rationale for all estimates, including estimated costs of rejected alternatives.

EPA expects to raise clarifying questions to the task force as needed to ensure full documentation of the rationale for the choice of each scenario-specific sampling design and the degree to which it incorporates random elements.

EPA will explain its decision to accept a PDS-based sampling design that incorporates random elements when feasible to the Human Studies Review Board (HSRB). Also EPA mentioned the HSRB plan for a workgroup to further review the question of sampling design for handler exposure research. EPA understands that the HSRB workgroup will not begin its work until it receives the report from the Agency's independent statistical consultant. If the HSRB offers further advice on the issue of sampling design for the handler research program, EPA intends to stand by its decision to support PDS with the above provisos.

6. EPA described its goal for streamlining the HSRB protocol and report review as a system that would normally involve a single HSRB review cycle for the scenario-specific design for each scenario and the first associated protocol, and a single HSRB review of the completed scenario-specific monograph and all supporting field study reports. Consistent with this goal, EPA intends to propose an expedited review by the Agency and the HSRB for subsequent protocols for approved scenarios, and individual field study reports, unless EPA finds they raise significant new ethical or scientific issues, or the HSRB has identified a basis for an exception to that process.

   EPA expects to continue to work with the AHETF to develop review procedures that are scientifically sound and compliant with the Human Studies Rule. These procedures will not be formally presented to the HSRB until the task forces have provided information needed to project the timing of future workload.

7. EPA responded to the AHETF's expressed concern for consistency in interpretation and decision-making. EPA cannot, of course, provide an unqualified guarantee that it will always accept data so long as the research was carried out according to the approved protocol, but EPA believes that it would be unfair to researchers for the Agency to reject data that are generated from carrying out a study in accordance with its approved test protocol, simply because different methodologies could have been used. Therefore, EPA's

practice and intention is to accept scientific data and information, developed following EPA-reviewed and approved test protocols, unless EPA determines that the data simply are not scientifically reliable or that the study was conducted in a manner that does not comply with EPA regulations for the protection of human research subjects.

8. EPA responded to AHETF's earlier recommendation that the HSRB be restricted to consideration of ethical issues by reminding the AHETF that the charge to the HSRB in the Human Studies Rule is to advise EPA on both scientific and ethical aspects of research with human subjects.

9. EPA responded to the AHETF request for a greater opportunity to present views and comments to the HSRB. EPA is reviewing how this could be done within the constraints of the Federal Advisory Committee Act. AHETF reminded EPA that registrants have routinely had opportunities for more substantive presentations and interaction with the EPA Scientific Advisory Panel (SAP) than has occurred under the HSRB's procedures.

10. EPA has issued PR Notice 2007-3 to encourage expansion of the membership of the AHETF. The Task Force thanked the EPA for issuing the PR Notice. AHETF indicated that some expressions of interest had been received but that no new members have yet been added. EPA expressed its openness to discuss other ways of increasing membership with the Task Force.

11. EPA does not plan to reinterpret or revise the definition of "research involving intentional exposure" to exclude scripted worker exposure studies. However research which EPA agrees is observational—that is, which does not meet the regulatory definition of "research involving intentional exposure"—will continue to be exempt from review by the HSRB.

12. EPA stated that it is interested in receiving scientifically robust data and generally will consider input from a range of external sources on the best way of conducting the research on pesticides. When appropriate, EPA will encourage the use of newer, better research methodology, including changes from the present guidelines. Science changes over time; EPA does not limit itself to just a single approach to communicating with researchers about appropriate testing methodologies.

13. EPA responded to AHETF questions concerning community involvement (CI), stating that there are no consistent definitions of community or community involvement relevant to pesticide handler exposure studies. The Human Studies Rule does not require addressing community involvement. Studies that do not involve affected communities can thus be argued to be in accord with the rule, unless they are otherwise in conflict with the rule.

    Nevertheless, CI is considered a best practice, particularly in a readily identifiable community or neighborhood. Further, EPA believes it is prudent for researchers to contact community organizations to obtain their input on their research and for its public relations value. Therefore EPA recommended that submissions should not be silent on community involvement but should document the investigator's consideration of the question and rationale for the approach chosen.,

Since few parallels exist between the kinds of community based research where CI activities have occurred and the type of work done by the AHETF, EPA offered to work with the AHETF to determine what might be feasible and useful. CI could be at a high-level to discuss the overall program with farmworker advocates or other interested groups, or it could be at the level of specific scenarios, or at a local level, in association with a specific field study. Possible examples: National Agricultural Aviation Association (NAAA) review of program and protocols related to aerial applications; farms with large workforces only a portion of which are involved in the study – explain the work to the whole workforce to minimize any concerns; use local workers or others to confirm accuracy of translation of recruitment and consent documents, etc.