MEMORANDUM

FROM: William L. Jordan
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Office of Pesticide Programs

THROUGH: Paul I. Lewis, Ph. D.
Executive Director
Human Studies Review Board
Office of the Science Adviser

TO: Celia B. Fisher, Ph. D.
Human Studies Review Board Chair

SUBJECT: Design of Sampling Strategies in Proposed Handler Research

As discussed during the October 2007 meeting of the Human Studies Review Board (HSRB), I am providing copies of materials addressing the issue of the sampling strategies to be used in the research proposed by the Agricultural Handlers Exposure Task Force (AHETF) and the Antimicrobial Exposure Assessment Task Force (AEATF), jointly referred to as the Task Forces. Specifically, here are:

1. The presentations made by the AHETF and AEATF at meetings on October 17 – 18, attended by EPA staff and Dr. Tapabrata Maiti, an associate professor of statistics at Iowa State University who consulted with EPA during and after the meetings with the Task Forces, and.

2. A report prepared by Dr. Maiti responding to questions posed by EPA following the October meeting with representatives of the Task Forces.

I also wish to inform you of the position of the Office of Pesticide Programs (OPP) regarding the issue of the sampling strategy to be used in the Task Forces' proposed research. OPP has carefully considered the views expressed by the HSRB in its June 2007 meeting and final report, as well as arguments advanced by the Task Forces and the advice from Dr. Maiti. We weighed a variety of factors in reaching our position, including:

- The effect of alternative sampling strategies on the potential scientific utility of data developed by the Task Forces;

- The financial and practical feasibility of alternative sampling strategies; and

- The impact of our choice on the timing of data development.

With the provisos stated below, we have determined that generation of handler exposure data using purposive diversity sampling (PDS) design is acceptable. We

reached this position based on the following considerations: much time and resources have already been spent by the AHETF and AEATF 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 be 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.

We expect to raise clarifying questions to the Task Forces 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.

As promised in the October 2007 meeting, OPP is planning to provide the HSRB with a presentation on this topic at the next HSRB meeting. We expect to explain more fully the basis for our decision and to respond to any questions from the Board.