UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 23, 2000

MEMORANDUM

SUBJECT: Review of Draft Study Protocol: Biomonitoring Assessment of Worker Exposure to Methyl Parathion During Cotton Scouting Following Applications of PENNCAP-M® Microencapsulated Insecticide

FROM: Jonathan Becker, Ph.D., Environmental Health Scientist
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THRU: Al Nielsen, Senior Scientist
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Please find attached a review of a study protocol addressing worker exposure (using biological monitoring) during cotton scouting following application of Penncap-M.

DB Barcode: D261454

Pesticide Chemical Code: 053501

Table 1: Identifying Information

Title:	Biomonitoring Assessment of Worker Exposure to Methyl Parathion During Cotton Scouting Following Applications of PENNCAP-M® Microencapsulated Insecticide
Sponsor(s):	Elf Atochem North America, Inc.; Agrichemicals Division; 2000 Market Street, 21st Floor; Philadelphia, PA 19103-3222
Testing Facility:	American Agricultural Services, Inc., 404 E. Chatham Street, Cary, NC 27511
Study Director:	Tommy R. Willard, Ph.D. (American Agricultural Services, Inc.)
Analytical Lab:	Morse Laboratories, Inc., 1525 Fulton Avenue, Sacramento, CA 95825
MRID Number:	449842-04
Protocol Date	01 November 1999
Other Identification Codes:	KP-2000-02

HED has reviewed this study protocol and determined that it is not acceptable as presented. Deficiencies and major issues are described below.

Workday length. The Agency considers 8-hours to be a full workday. The Agency will "scale" shorter exposure durations to estimate the pesticide exposures for a full workday. For example, if the test subject conducts "one typical work-cycle" which lasts for 2 hours, the Agency will scale (i.e., multiply) the exposures (including ½ LOD for non-detects) by 4 to estimate the test subject's exposures for a 8-hour workday. Rather than conducting "one typical work-cycle" as described on page 9, the Agency suggests having the test subjects scout cotton for one full workday, so an adjustment for exposure duration is not required. Please clarify the protocol, as it indicated that the test subjects will conduct both "one full day of cotton scouting" (page 19) and "one full work cycle (~2 hr of actual cotton scouting....)" (page 20).

Scout clothing. Because this study is being conducted **after** the entry restriction interval has expired, there are no applicable product label requirements for work clothing or PPE. The Agency consider the following to be typical work clothing for cotton scouts: long pants, long-sleeved shirt, no gloves. Detailed descriptions of the clothing worn by the scouts must be included in the study report. **The use of label-specified handler or early-entry protective clothing and equipment (other than the typical work clothing listed above) will invalidate the study.**

Prohibited materials and worker activities (Appendix 2). Appendix 2, *Proposed Restrictions on Chemical Contact and Subject Activity*, was not included in the protocol. The Agency requests the opportunity to review this Appendix prior to initiation of the study.

Source of urine for field fortification samples. The source of the urine used for field fortifications should be specified in the protocol.

Field Fortifications. The protocol (page 22) indicates two field fortification levels will be included in the study (LOQ and 100X LOQ). Depending on the anticipated analyte levels, an additional field fortification at either 10X LOQ or 1000X LOQ might be added.

Total urinary output. Please verify that the **total** 72-hour urinary output (collected in 12-hr. intervals) for the test and control subjects will be collected and analyzed.

Exclusion of outliers (page 12). All raw and adjusted data should be included in the final report. Statistical "outliers" may be identified, but should not be excluded from the analysis.

Relationship of this study to DFR study. The interrelationship of this study with that of the DFR study should be clearly explained.