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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 27, 2000

MEMORANDUM

SUBJECT: Review of Draft Study Protocol: Postapplication Exposure Monitoring of Penncap-M® During Walnut Harvesting Utilizing Biological Monitoring and Soil Residue Dissipation

FROM: Jonathan Becker, Ph.D., Environmental Health Scientist
Reregistration Branch II
Health Effects Division (7509C)

TO: Laura Parsons
Reregistration Branch I
Special Review and Reregistration Division (7508W)

THRU: Al Nielsen, Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

Please find attached a review of a study protocol addressing post-application exposure monitoring of Penncap-M® during walnut harvesting utilizing biological monitoring and soil residue dissipation.

DB Barcode: D261462

Pesticide Chemical Code: 053501

Table 1: Identifying Information

Title:	Postapplication Exposure Monitoring of Penncap-M® During Walnut Harvesting Utilizing Biological Monitoring and Soil Residue Dissipation
Sponsor(s):	Elf Atochem North America, Inc.; Agrichemicals Division; 2000 Market Street, 21st Floor; Philadelphia, PA 19103-3222
Testing Facility:	Excel Research Services, Inc., 3021 W. Dakota, Suite 110, Fresno, CA 93722
Study Director:	Tami I. Belcher (Excel Research Services, Inc.)
Analytical Lab:	Morse Laboratories, Inc.,1525 Fulton Avenue, Sacramento, CA 95825
MRID Number:	449842-07
Protocol Date	01 November 1999
Other Identification Codes:	KP-2000-06, ERS-20004

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

Activity of Workers. EPA has no information to indicate that hand-raking walnuts from around tree trunks and off berms will result in the highest total exposure (combined dermal and inhalation routes of exposure). The study should incorporate all other job classes of postapplication activities into the design.

Length of Workday. EPA considers 8-hours to be a standard workday. Shorter exposure durations will be scaled up to represent a full work day. The consequences of this adjustment should be carefully considered by the registrants in designing the study.

Total Urine. Verify that total urinary output is collected from each worker for the entire 3-day postapplication monitoring period.

Work Clothing. Clothing for all replicates should be identical and explicitly described in the protocol. EPA considers long-sleeved shirts with long pants to be standard postapplication worker clothing.

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

Relationship of this study with other studies being conducted. The interrelationship of these studies (harvester biomonitoring and soil residue) with that of the DFR study should be clearly explained.

Number of Geographic Locations. The OPPTS Guidelines require the study to be conducted in three geographic locations. The protocol should include additional justification why the study will be conducted at only two sites.