UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

(2PP)

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Certified Mail

Melvin K. Tolliver
Bayer Corporation
Agriculture Division
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013

Subject: Fenamiphos Reregistration
Hazard Identification Assessment Review Committee Report
Dated 9/18/97

Dear Mr. Tolliver:

The Health Effects Division's Hazard Identification Assessment Review Committee recently met to evaluate the toxicological data base of fenamiphos with special emphasis on reproductive, developmental and neurotoxicity data. These data were reviewed specifically to address the sensitivity of infants and children from exposure to fenamiphos as required by the Food Quality Protection Action of 1996. The Agency concluded that:

1. Acute Dietary Risk Assessment

The endpoint selected for acute dietary risk assessment is based on inhibition of plasma (males and females) and red blood cell (males) cholinesterase activity at 0.37 mg/kg/day (LOEL) in an acute neurotoxicity study with rats. A NOEL was not established in this study. The Committee determined that an additional UF of 10 to account for enhanced sensitivity to infants and children (as required by FQPA) should be reduced to 3 based on the lack of a NOEL in this study.

(1)

CONCURRENCES

SYMBOL	7508	SRRD/RAD						
SURNAME	Loranger	Woolley						
DATE	12/15/97	12/16/97						

Chronic Dietary Risk Assessment

The endpoint selected for chronic dietary risk assessment is based on plasma ChEI observed at 0.3 mg/kg/day (LOEL) in a 1-year feeding study in dogs. The NOEL was 0.01 mg/kg/day. An UF of 100 was applied to the NOEL: 10 to account for intra-species and a 10 for inter-species variations. Thus a RfD of 0.0001 mg/kg/day was derived.

For chronic dietary risk assessment, the Committee determined that an additional UF of 10 to account for enhanced sensitivity of infants and children (as required by FQPA) is not warranted. The present UF of 100 is adequate to ensure the protection of this population from exposure to fenamiphos since there was no indication of increased sensitivity to young animals following pre-and/or post-natal exposure to fenamiphos as shown below:

a. Developmental toxicity studies showed no increased sensitivity to fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits.

b. A 2-generation and a 3-generation reproduction toxicity studies in rats showed no increased sensitivity to pups as compared to adults.

A copy of the memo dated 9/18/97 is enclosed for your review. You are welcome to submit comments to this document. Your comments should be sent directly to Judy Loranger. If you have any questions concerning this letter, please contact Judy Loranger at (703)-308-8056.

Sincerely yours,

Walter I. Waldrop, Chief
Reregistration Branch III
Special Review and Reregistration Division (7508W)

Enclosure