MEMORANDUM 2/24/98

Subject: Fenitrothion HED RED Chapter. Update to Consider FQPA Requirements.
PC Code 105901, Case No. 0445
DP Barcode D243479

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This memorandum and attachments update the HED RED Chapter for Fenitrothion (John C. Redden, 5/7/94) taking into consideration requirements of the 1996 Food Quality Protection Act (FQPA). Attachments include the original HED RED Chapter (attachment 1), the most recent Hazard Identification Review Committee (HAZID) report (attachment 2, Jess Rowland, 10/8/97, and 2/19/98 addendum), the most recent DRES analysis (attachment 3, Stephen A. Schaible, 5/25/93), and wheat gluten production information (attachment 4, Frank Hernandez 5/17/93). The Agency RED for fenitrothion was issued June 1995.

Fenitrothion is an organothiophosphate insecticide/acaricide. Cumulative risk assessment considering risks from other pesticides which have a common mechanism of toxicity is not addressed in this document.

Following the issuance of the initial HED RED Chapter, all uses of fenitrothion were canceled excluding EPA Reg. Nos. 506-174 and 506-175, which are ant and roach bait traps, respectively. Additionally, the tolerance established to cover imported wheat gluten remains in effect (15 ppm, 40 CFR 18.2200). Only these uses are considered in this update. Considering only these uses, risk estimates resulting from exposure to fenitrothion are expected to be insignificant as detailed below.

Fenitrothion is an organothiophosphate insecticide/acaricide. The technical material is acute

toxicity category 2 for oral, dermal, and inhalation toxicity, as well as for eye effects, and dermal irritation. The predominant toxic effect, which is the toxic effect associated with all risk assessment endpoints, is cholinesterase inhibition and associated clinical signs of cholinesterase inhibition. Developmental toxicity was observed in the rat, but only at doses at which significant maternal toxicity was observed; no developmental effects were observed in the rabbit developmental study. No evidence of carcinogenicity was seen in any study.

Exposures resulting from proper use of the ant and roach bait traps are expected to be insignificant. HED does not estimate risks for these types of uses because of this low potential for exposure. However as with other bait trap uses, the possibility of children acquiring these bait traps, which are placed around the home, and consuming the contents may exist. If this were to occur, risk concern would exist for a child consuming the contents of a single bait station containing fenitrothion. Since this is a generic issue for bait stations for many pesticides, it will not be addressed further here. We note that for both of the bait station products, recent Notices of Pesticide Reregistration have been unconditionally issued (EPA Reg. No. 506-174 issued 7/17/97; EPA Reg. No. 506-175 issued 7/2/97).

As described in the original HED RED Chapter, a tolerance level of 15 ppm was established to cover residues of fenitrothion in wheat gluten imported from Australia. EPA's Dietary Risk Evaluation System (DRES) does not contain consumption values for wheat gluten; therefore, average *per capita* consumption of wheat gluten was estimated using production and import data. The estimated exposure of 0.000044 mg/kgBW/day resulted in a chronic dietary risk estimate of 3% RfD. This is likely to be a high end estimate of chronic dietary risk since it uses tolerance level residues.

Although an acute dietary endpoint and NOEL were identified for fenitrothion (NOEL = 12.5 mg/kgBW/day, LOEL = 50 mg/kgBW/day based on tremors, ataxia, gait incapacitation, and other FOB parameters), an acute dietary risk assessment was not performed for the original HED RED Chapter because data to estimate single-day consumption of wheat gluten are not available. Rather, it was concluded that since the acute NOEL is 100-fold greater than the NOEL used to set the RfD, and calculations using the RfD indicate minimal chronic dietary risk, there is no concern for acute dietary exposure. However, using the average *per capita* exposure estimate (0.000043 mg/kgBW/day, based on tolerance level residues in wheat gluten), with the acute dietary NOEL (12.5 mg/kgBW/day) results in an estimated acute dietary MOE $\geq$ 290,000. Therefore, while there are uncertainties in the estimated risk due to uncertainties in the consumption estimate, this extremely high acute dietary MOE indicates that risks from this use will be insignificant.

The HED Hazard Identification Committee (HAZID) met on 10/8/97 to examine the hazard data base for fenitrothion considering the requirements of the 1996 Food Quality Protection Act (FQPA) (Jess Rowland, 10/8/97, attached). The committee examined the results of acute delayed, acute, and subchronic neurotoxicity studies, rat and rabbit developmental studies, and a two-generation rat reproduction study. The committee drew two major conclusions: that a developmental neurotoxicity study is not required, and that the hazard data indicate that the FQPA 10X factor should be removed. Regarding the need for a developmental neurotoxicity

study, the committee concluded that since no neuropathology was observed in any of the three neurotoxicity studies available, and since no increased susceptibility was observed for fetuses or pups in the developmental and reproduction studies, sufficient information is available to characterize the hazard to infants and children; therefore, a developmental toxicity study is not needed. The decision to remove the 10X factor relative to hazard considerations was made based on having a complete hazard data base relative to infants and children, and the lack of increased susceptibility in the fetuses and/or pups in the developmental and reproduction studies.

An assessment for the potential contamination of drinking water has been provided by EFED (Patricia D. Jennings to Chris Olinger, 11/7/97, attached). The review concluded the following: "Based on the proposed use of fenitrothion as roach, water bug, palmetto bug, and ant bait, releases of fenitrothion to ground water and surface water are not expected."

Since exposure from residential uses and water are expected to be insignificant, an aggregate exposure assessment for fenitrothion would include consideration of exposures only from food.

Please let us know if further information is required.

Attachments:
Attachment 1: HED RED Chapter (John C. Redden, M.S. to Lois Rossi, 5/94)
Attachment 2: HAZID Report (Jess Rowland, 10/8/97)
Attachment 3: DRES Chronic Dietary Assessment (Stephen A. Schaible, 5/25/93)
Attachment 4: Wheat Gluten Consumption and Australian Imports (Frank Hernandez, 5/17/93)

cc with attachments:
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cc without attachments:
LAN files