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

013022

DEC 17 1998

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Isoxaflutole (PC Code 123000): Reconsideration of the "Food Quality Protection Act"-Factor Previously Applied by the RfD/Hazard Identification Committees.

From: George Z. Ghali, PhD G. Ghali
Science Analysis Branch
Health Effects Division (7509C)

To: William Burnam, Chief
Science Analysis Branch
Health Effects Division (7509C)

Between August 1996 and April 1998, the Health Effects Division (HED)-Reference Dose (RfD) Committee (currently the Hazard Identification Committee or HIARC) was requested to assess an appropriate Uncertainty Factor (UF) to account for possible extra sensitivity of infants and children to pesticidal chemicals under the new Food Quality Protection Act (FQPA).

In April 1998, the FQPA Safety Factor Committee was subsequently formed for the expressed purpose of determining the appropriate UF for all pesticides evaluated for FQPA compliance considering both the hazard and exposure data. Therefore, the uncertainty factor previously determined by either the HED-RfD Committee or the HIARC was removed before submission of these chemicals to the FQPA Safety Factor Committee.

The following are the calculations for both the acute and chronic RfD after the removal of the FQPA uncertainty factor:

A. Acute Oral RfD:

No acute oral RfD was established.

B. Chronic Oral RfD:

The chronic oral RfD is based on a chronic toxicity study in

rats with a NOAEL of 1.74 mg/kg/day, based on liver, thyroid, ocular and nervous system toxicity observed in males at the next higher dose level (LOAEL) of 17.6 mg/kg/day. An uncertainty factor of 100 was applied to account for interspecies extrapolation, and 10 for intraspecies variability. On this basis the RfD was calculated to be 0.017 mg/kg/day. It should be noted that the FQPA factor of 3 was removed (this factor was originally applied to account for the lack of a NOEL in the developmental toxicity study in rabbits and for FQPA considerations).