

comprehensive series of required tests. The probability of any such effect due to agricultural uses of fenpyroximate is negligible.

C. Aggregate Exposure

1. *Dietary exposure.* The potential dietary exposure to fenpyroximate has been calculated from the proposed tolerances for use on cotton, grapes, and pome fruit. These very conservative chronic dietary exposure estimates used the tolerance value for all the raw agricultural commodities. In addition, these estimates assume that 100% of the crops contain fenpyroximate residues.

i. *Food.* Chronic dietary exposure to fenpyroximate was estimated on the basis of 100% crop treatment for cotton, grapes, and pome fruit and assuming tolerance level residues on these crops. These estimated exposures were compared to the chronic dietary RfD for fenpyroximate, which has already been established by EPA at 0.010 milligrams/kilogram/day (mg/kg/day), in connection with the import tolerance on wine grapes and hops.

ii. *Drinking water.* Laboratory and field data have demonstrated that fenpyroximate is immobile in soil and will not leach into ground water. Other data show that fenpyroximate is virtually insoluble in water. As a result, NAI concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential for other miticides was conducted using EPA's Pesticide Root Zone Model (PRZM) and Screening Concentration in Ground Water (SCI-GROW). Based on this screening assessment, the potential concentrations of fenpyroximate and z-isomer in water at depths of 1 and 2 meters are essentially zero (<1 part per trillion (ppt)). Surface water concentrations using PRZM and EXAMS were predicted in the simulated pond of 0.0242 part per billion (ppb).

2. *Non-dietary exposure.* There are no registered or proposed residential uses of fenpyroximate. Thus, a residential exposure assessment is not required. Exposure to fenpyroximate for the mixer/loader/ground boom applicator was calculated using the Pesticides Handlers Exposure Data base (PHED). These PHED assessments were based on a 70 kg operator treating <50 acres per day using ground boom equipment on both apples and grapes and 80 acres per day on cotton by ground application with an operator treating at a maximum use rate of 0.1 lb active ingredient per acre. All mixer/loaders and workers/operators were assumed to be wearing

gloves, long pants and long-sleeved shirts.

D. Cumulative Effects

In consideration of potential cumulative effects of fenpyroximate and other substances that may have a common mechanism of toxicity, to our knowledge there are no currently available data or other reliable information indicating that any toxic effects produced by fenpyroximate would be cumulative with those of other chemical compounds; thus only the potential risks of fenpyroximate have been considered in this assessment of its aggregate exposure.

E. Safety Determination

1. *U.S. population*—i. *Acute.* Using the 100% crop treatment scenario the acute population adjusted dose (aPAD) for the general population is 0.002309 mg/kg/day. Of the standard subgroups which are analyzed by the Dietary Exposure Evaluation Model (DEEM), the subgroup with the highest exposures is infants (<1 year) with an acute dietary exposure estimated at 0.006368 mg/kg/day (12.74% of the acute reference aRfD). For children in the age brackets 1–6 years and 7–12 years, the dietary exposures are approximately 0.004716 mg/kg/day (9.43% of the aRfD) and 0.002581 mg/kg/day (5.16% of the aRfD), respectively. Males and females aged 13 and older have an estimated acute dietary exposure of 0.001054 and 0.000911 mg/kg/day, respectively (2.11% and 1.82% of the aRfD, respectively). Even applying the Food Quality Protection Act (FQPA) factor of 10X to females aged 13 and older the percent aRfD utilization is only a modest 11.82%. All values for percentage utilization of the aRfD are well below 100% and no value exceeds 12.74%.

ii. *Chronic.* Of the standard subgroups which are analyzed by the DEEM, and using the conservative estimates, of 100% crop treatment scenario, the chronic population adjusted dose (cPAD) for the general population, is approximately 0.0002579 mg/kg/day (which is 2.58% of the RfD). This value is based on the no observed adverse effect level (NOAEL) of 0.97 mg/kg/day observed in the chronic rat feeding study, the worse case estimate of chronic dietary exposure of fenpyroximate from cotton, grape, and pome fruit and a safety (uncertainty) factor of 100.

2. *Non-dietary exposure*—i. *Acute.* The margins of exposure relative to the acute dietary endpoint (5 mg/kg/day) are all in excess of 1,000. Therefore, there is a reasonable certainty that no

harm will occur from acute exposure to crops treated at the maximum labeled use rates and minimum preharvest intervals for fenpyroximate. Worker exposure (mixer/loader and applicator) estimates provide for margins of safety of >100 in all scenarios. Worker exposure is therefore expected, to a reasonable degree of scientific certainty, to be without harm. Based on the above, exposures of the U.S. population to fenpyroximate associated with the uses addressed in this reduced risk submission are expected, to a reasonable degree of scientific certainty, to be without harm.

ii. *Chronic.* The margins of exposure relative to the chronic dietary endpoint are all in excess of 1,700. Therefore, there is a reasonable certainty that no harm will occur from chronic exposure to crops treated at the maximum labeled use rates and minimum preharvest intervals for fenpyroximate.

3. *Infants and children*—i. *Acute.* Using the 100% crop treatment scenario, the subgroup with the highest exposures is infants (<1 year) with an acute dietary exposure estimated at 0.006368 mg/kg/day (12.74% of the aRfD). For children in the age brackets 1–6 years and 7–12 years, the acute dietary exposures are approximately 0.004716 mg/kg/day (9.43% of the aRfD) and 0.002581 mg/kg/day (5.16% of the aRfD), respectively. Acute dietary exposure of infants and children is therefore expected, to a reasonable degree of scientific certainty, to be without harm. Based on the above, exposures of infants and children to fenpyroximate associated with the uses addressed in this reduced risk submission are expected, to a reasonable degree of scientific certainty, to be without harm.

ii. *Chronic.* Using the 100% crop treatment scenario, infants (less than 1 year) have the highest chronic exposure (0.0009228 mg/kg/day, which is 9.23 % of the RfD). For children in the age brackets 1–6 years and 7–12 years, the dietary exposures are approximately 0.0005244 mg/kg/day (5.24% of the RfD) and 0.0002733 mg/kg/day (2.73% of the RfD), respectively. Chronic dietary exposure of the infants and children is therefore expected, to a reasonable degree of scientific certainty, to be without harm.

iii. *Conclusion.* There is a complete toxicity data base for fenpyroximate and exposure data are conservatively estimated based on data that reasonably account for potential exposures. Based on these risk assessments, Nichino America, Inc. concludes that, there is a reasonable certainty that no harm will result to infants and children from