

TIER I—CALCULATED CHRONIC DIETARY EXPOSURES TO THE TOTAL U.S. POPULATION AND SELECTED SUB-POPULATIONS TO FLUFENPYR-ETHYL RESIDUES IN FOOD (CPAD = 0.05 MG/KG/DAY)

Population Subgroup	Exposure (mg/kg/day)	Percent of cPAD
Total U.S. population	0.000025	0.05
Males (13 - 19 years)	0.000032	0.06
Females (13 + (nursing))	0.000019	0.04
Females (13 + (pregnant/not nursing))	0.000021	0.04
Children (7 - 12 years)	0.000043	0.09
Children (1 - 6 years)	0.000056	0.11
All infants (< 1 year)	0.000067	0.13
Non-nursing infants	0.000082	0.16
Nursing infants	0.000017	0.03

ii. *Drinking water.* Since flufenpyr-ethyl is applied outdoors to growing agricultural crops and can be applied by aircraft, the potential exists for the parent or its metabolites to reach ground water or surface water that may be used for drinking water. Because of the physical and environmental fate properties of flufenpyr-ethyl, it is unlikely that flufenpyr-ethyl or its metabolites can leach to potable ground water. To quantify potential exposure from drinking water, surface water concentrations for flufenpyr-ethyl were estimated using Generic Expected Environmental Concentration (GENEEC 1.2.). The 56-day average GENEEC concentration was 0.027 ppb. Using standard assumptions about body weight and water consumption, the maximum chronic exposure from this drinking water would be 0.000000763 and 0.00000267 mg/kg/day for adults and children, respectively; 0.0053 percent of the cPAD of 0.05 mg/kg/day for children. The contribution of drinking water to chronic dietary exposures is much smaller than that from food, and adds negligible risk.

2. *Non-dietary exposure.* Flufenpyr-ethyl is proposed only for agricultural uses and no homeowner, turf, or industrial uses. Thus, no non-dietary risk assessment is needed.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that the Agency must consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Available information in this context include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for

understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

There are other pesticidal compounds that are structurally related to flufenpyr-ethyl and may have similar effects on animals. In consideration of potential cumulative effects of flufenpyr-ethyl and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by flufenpyr-ethyl would be cumulative with those of other chemical compounds. Thus, only the potential risks of flufenpyr-ethyl have been considered in this assessment of aggregate exposure and effects.

Valent will submit information for EPA to consider concerning potential cumulative effects of flufenpyr-ethyl consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL-5734-6) and other subsequent EPA publications pursuant to the Food Quality Protection Act of 1996 (FQPA).

E. Safety Determination

The FQPA introduced a new standard of safety, a reasonable certainty of no harm. To make this determination, at this time the Agency should consider only the incremental risk of flufenpyr-ethyl in its exposure assessment. Since the potential chronic and acute

exposures to flufenpyr-ethyl are small (<100% of cPAD and aPAD) the provisions of the FQPA will not be violated.

1. *U.S. population—i. Acute risk.* There is no acute oral toxic endpoint available, so no risk analysis was performed.

ii. *Chronic risk.* Using the dietary exposure assessment procedures described above for flufenpyr-ethyl, calculated chronic dietary exposure resulting from residue exposure from proposed uses of flufenpyr-ethyl is minimal. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is 0.064 to 0.042% of the cPAD. Addition of the small but worse case potential exposure from drinking water (calculated above) increases exposure by only 0.000000763 mg/kg/day (0.0053% of cPAD) and the maximum occupancy of the cPAD from 0.064% to 0.066%. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the cPAD. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. population and many non-child/infant subgroups from aggregate, chronic exposure to flufenpyr-ethyl residues.

2. *Safety factor for infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of flufenpyr-ethyl, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to 10-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.