

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUFENACET

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.0017	23	9.9	0.21	46
All Infants	0.0017	23	9.9	0.21	13
Children (1-2 yrs)	0.0017	48	9.9	0.21	9
Children (3-5 yrs)	0.0017	42	9.9	0.21	10
Children (6-12 yrs)]	0.0017	29	9.9	0.21	12
Youth (13-19 yrs)	0.0017	21	9.9	0.21	41
Adults (20-49 years)	0.0017	20	9.9	0.21	47
Females (13-19 years)	0.0017	17	9.9	0.21	42

The EECs are less than calculated DWLOCs for acute exposure to flufenacet in drinking water, except for the population subgroup, children 1-2 years old, where the EEC marginally exceeds the DWLOC.

In evaluating the acceptability of these estimated risks, EPA has taken into account that the risk assessment was performed by estimating exposure at the 99.9th percentile of exposure. As EPA has explained in its policy regarding use of population percentiles in estimating exposure, EPA generally uses the 95th percentile when conducting an exposure assessment with unrefined residue values (i.e. assuming all covered food contains tolerance level residues) and the 99.9th percentile when using highly refined residue values (i.e. monitoring values). See U.S. EPA, Office of Pesticide Programs, Choosing A Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern 17 (March 16, 2000) (<http://www.epa.gov/pesticides/trac/science/trac2b054.pdf>). The residue values used in the flufenacet risk assessment fall somewhere between highly refined and unrefined. Although the Agency did use data bearing on percent crop treated, three other aspects of the assessment made it not particularly refined, and therefore, somewhat conservative (i.e. tending to overstate exposure). First, EPA assumed tolerance level residues for all crops covered by tolerances designed to address the possibility of flufenacet residues being present in crops grown at a later date in the same field as the treated crop. These rotational crop tolerances include rice and sorghum. Further, compounding this conservative assumption, EPA assumed that two percent of all of the crops covered by rotational crop tolerances would contain

flufenacet residues even though the treatment rate for wheat and soybeans was at a one percent level (only corn was at the two percent level) and it is unlikely, in any event, that the crops covered by the rotational crop tolerances would, in their entirety, be grown in a rotational program.

Second, and probably most important, for those crops for which EPA did not assume tolerance level residues (corn, wheat, and soybeans) EPA did not use monitoring data (i.e. data collected from food as it moves in the channels of trade) but data from crop field trials. Crop field trials are studies conducted to determine the maximum residue levels that can occur under the limits imposed by the pesticide's label. Accordingly, such studies involve applying the pesticide, pursuant to its label, the maximum number of times at the maximum application rate and harvesting the crop as promptly as soon as permitted following the last pesticide treatment. These studies overstate the residue levels that consumers are exposed to for two reasons. First, in crop field studies, residue levels are measured at harvest and thus do not reflect the degradation that generally occurs during the production, shipping, and storage of food prior to sale to the consumer. Second, farmers are not required to apply pesticides in the manner used in crop field trials but generally may use lower amounts than those specified on the label, apply the pesticide less frequently than the number of applications permitted by the label, and wait longer to harvest the crop than the minimum pre-harvest interval prescribed by the label. See 7 U.S.C. 136a(ee). Such practices reduce residue values, normally by significant amounts. With flufenacet, the decrease will be even more significant than usual

because some of the field trial data are based upon an application rate of 0.9 lbs. a.i. acre per season v.s. the label rate of 0.79 lbs. a.i. acre per season for field corn and 0.9 lbs. a.i. acre per season v.s. the label rate of 0.45 lbs. a.i. per acre per season for soybeans.

A third aspect of the flufenacet exposure assessment that overstated residue levels was the fact that EPA did not use processing reduction factors. Processing studies are performed in order to show whether or not residues concentrate in processed commodities of the RAC. For example wheat grain, may be processed into bran, flour, middlings, shorts and germ. Processing studies frequently show residues decreasing in the processed commodities. If the residues decrease in the processed commodity, we may be able to determine a reduction factor. The concentration and/or reduction factors are directly applied to the residue level used in the dietary exposure assessment for that commodity. The processing studies for flufenacet treated corn and soybeans showed no detectable residues. However, the Agency for this risk assessment assumed the residues in the raw agricultural commodity were carried through undiminished to the processed commodities.

As EPA has made clear, even when an exposure assessment is based on highly refined data, an indication that exposure at the 99.9th percentile poses a risk of concern is merely the starting point for assessing the ultimate safety of the pesticide. EPA has detailed a number of steps that are important to assess the accuracy of any 99.9th percentile estimate including sensitivity analyses and scrutiny of data inputs. When an assessment does not rely on highly refined exposure data there is an even greater need for close examination of