

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Chronic dietary (all populations)	NOAEL = 0.6 mg/kg/day UF = 100 Chronic RfD = 0.006 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.0006 mg/kg/day	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males.
Oral nondietary (all durations)	NOAEL = 0.6 mg/kg/day	LOC for MOE = 1,000 (Residential)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males.
Dermal (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (dermal absorption rate = 5%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males.
Inhalation (all durations) (Residential)	Oral study NOAEL = 0.6 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential) LOC for MOE = 100 (Occupational)	2-Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F1 generation males.
Cancer (oral, dermal, inhalation)	Likely carcinogen for humans based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice. Quantification of risk based on most potent unit risk: male mouse liver adenoma and/or carcinoma combined tumor rate. The upper bound estimate of unit risk, Q1* milligrams/kilogram/day (mg/kg/day) <sup>-1</sup> is $3.77 \times 10^{-2}$ in human equivalents.		

\*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established for the combined residues of thiamethoxam, in or on a variety of raw agricultural commodities (RAC). The following RAC's have established tolerances: Barley, canola, cotton, sorghum, wheat, tuberos and corm vegetables crop subgroup, fruiting vegetables, crop group, tomato paste, cucurbit vegetables crop group, pome fruits crop group, milk and the meat and meat by products of cattle, goats, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to

the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues and 100% crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic exposure estimates are based on Tier 3 analyses that incorporate anticipated residues and percent crop treated (PCT) for most commodities.

iii. *Cancer.* Cancer dietary exposure has been estimated using the DEEM-FCID version 1.3. The cancer exposure estimates are based on Tier 3 analyses that incorporate anticipated residues and PCT for most commodities.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided

5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To