

(aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach,

a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for thiacloprid used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIACLOPRID FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All population groups)	NOAEL = 3.1 mg/kg UF = 300* Acute RfD = 0.01 mg/kg.	Special FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.01 mg/kg	Acute Neurotoxicity - rats LOAEL = 11 mg/kg/day based on decreased motor activity in females.
Chronic Dietary (All populations)	NOAEL = 1.2 mg/kg/day UF = 300* Chronic RfD = 0.004 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.004 mg/kg/day	Chronic feeding in rats. LOAEL = 2.5 mg/kg/day based on hepatic hypertrophy and cytoplasmic change and thyroid hypertrophy and retinal degeneration.
Cancer (Oral, dermal, inhalation)	$Q_1^* (\text{mg/kg/day})^{-1} = 4.06 \times 10^{-2}$	Classified as a likely human carcinogen based on thyroid tumors and uterine tumors in rats and ovary tumors in mice	

UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* There are no tolerances established for residues of thiacloprid. Risk assessments were conducted by EPA to assess dietary exposures from thiacloprid 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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: A moderately refined, Tier 3 acute dietary exposure assessment, which incorporated field trial data, estimates of % market share, and empirical processing factors, was conducted for the general U.S. population and various population subgroups. Monitoring data are not available for thiacloprid as it is a new chemical. EPA estimated

exposure at the 99.9th exposure percentile.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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 chronic exposure assessments: A partially refined, Tier 3 chronic dietary exposure assessment, which incorporated field trial data, empirical processing factors, and projected percent crop treated estimates, was conducted for the general U.S. population and various population subgroups. Monitoring data are not available for thiacloprid as it is a new chemical.

iii. *Cancer.* A cancer assessment was performed using the same assumptions as the chronic assessment in Unit III.C.1. ii. The cancer dietary exposure estimate for the general U.S. population is 1.3×10^{-6} .

iv. *Anticipated residue and percent crop treated (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