

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIPROXYFEN FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF and LOC for Risk Assessment | Study and Toxicological Effects |
|-----------------------------------|-----------------------------------|-------------------------------------|---------------------------------|
| Cancer (oral, dermal, inhalation) | Cancer classification ("Group E") | Risk Assessment not required | No evidence of carcinogenicity |

¹ UF = uncertainty factor, FQPA SF = Food Quality Protection Act safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, MOE = margin of exposure

*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.* Tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen 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. An aRfD for females 13–50 years old and the general population, including infants and children, was not selected because an acute oral endpoint attributed to a single-dose exposure could not be identified in any of the toxicology data base, including maternal toxicity in the developmental toxicity studies. Thus, the risk from acute exposure is considered negligible.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDTM), version 1.3 analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (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. A tier 1 (assumptions: Tolerance level residues and 100 percent crop treated (PCT)) was conducted.

b. The established tolerances of 40 CFR 180.510 and the new tolerances established in this document were included in the analysis.

c. Anticipated residues and PCT were not used in this analysis.

d. The processing factors applied were the DEEM default values.

For chronic dietary risk, EPA's level of concern is >100% cPAD. Dietary exposure estimates for representative

population subgroups are presented in Table 3 of this unit. The results of the chronic analysis indicate that the estimated chronic dietary risk associated with the existing and EPA-recommended uses of pyriproxyfen is below EPA's level of concern.

TABLE 3.—SUMMARY OF RESULTS FROM CHRONIC DEEMTM ANALYSIS OF PYRIPROXYFEN

| Subgroup | Exposure (mg/kg/day) | % cPAD |
|----------------------------|----------------------|--------|
| U.S. Population (total) | 0.003836 | 1.1 |
| All Infants (< 1 year old) | 0.006852 | 2.0 |
| Children 1–2 years old | 0.013707 | 3.9 |
| Children 3–5 years old | 0.010107 | 2.9 |
| Children 6–12 years old | 0.005969 | 1.7 |
| Youth 13–19 years old | 0.003389 | 1.0 |
| Adults 20–49 years old | 0.002658 | 0.8 |
| Females 13–49 years old | 0.002702 | 0.8 |
| Adults 50+ years old | 0.002676 | 0.8 |

iii. *Cancer.* In accordance with the Agency's 1986 Guidelines for Carcinogenic Risk Assessment, the RfD/Peer Review Committee classified pyriproxyfen as a "Group E" chemical-negative for carcinogenicity to humans. This classification is based on the lack of evidence of carcinogenicity in mice and rats.

iv. *Anticipated residue and PCT information.* Anticipated residues and PCT information was not used in the Agency's assessment.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient

monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyriproxyfen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyriproxyfen.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCIGROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD.