

to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (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 quinoxifen used for human risk assessment is shown in Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age) and acute dietary (general population including infants and children)	Not applicable	Not applicable	There were no toxic effects attributable to a single dose. Therefore, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old
Chronic dietary (all populations)	NOAEL= 20 mg/kg/day UF = 100 Chronic RfD = 0.20 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/ FQPA SF = 0.20 mg/kg/day	Combined chronic toxicity/carcinogenicity study in rat LOAEL = 80 mg/kg/day, based upon increases in severity of chronic progressive glomerulonephropathy in the males and minimal decreases in body weight and body weight gain in both sexes
Cancer (oral, dermal, inhalation)	Classified as not likely to be carcinogenic to humans	Not applicable	No evidence of carcinogenicity in rats and mice

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Quinoxifen is a new chemical and therefore, these are the first tolerances to be established for the residues of quinoxifen. Risk assessments were conducted by EPA to assess dietary exposures from quinoxifen in food as follows:

i. *Acute exposure.* Quantitative 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. There were no toxic effects attributable to a single dose. Therefore, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13–50 years old. As a result, no acute risk is expected from exposure to quinoxifen and hence no quantitative acute dietary risk assessment was performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data 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: An unrefined, Tier 1 chronic-dietary exposure assessment using tolerance-level residues and assuming 100% CT for all proposed commodities, and default DEEM Version 7.76 processing factors for all commodities.

iii. *Cancer.* Quinoxifen has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative risk assessment was not conducted to assess cancer risk.

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

monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for quinoxifen 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 quinoxifen.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that