

the RfD is equal to the NOAEL divided by the appropriate UF ( $RfD = NOAEL/UF$ ). Where an additional safety factors (SF) is retained due to concerns unique 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  $1 \times 10^{-6}$  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 ( $MOE_{cancer} = \text{point of departure}/\text{exposures}$ ) is calculated. A summary of the toxicological endpoints for boscalid used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BOSCALID 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	No appropriate endpoint identified	Not Applicable	Not Applicable
Chronic Dietary (All populations)	NOAEL = 21.8 mg/kg/day Chronic RfD = 0.218 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/ FQPA SF = 0.218 mg/kg/day	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Incidental Oral (Short and intermediate term residential only)	NOAEL = 21.8 mg/kg/day	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Dermal (All Durations)	Oral study NOAEL = 21.8 mg/kg/day (dermal absorption rate = 15%)	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Inhalation (All Durations)	Oral study NOAEL = 21.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Cancer (oral, dermal, inhalation)	Classification: Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.		

UF = uncertainty factor, FQPA SF = Special FQPA 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, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

\* 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.* These are the first food uses and tolerances for residues of boscalid, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from boscalid 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. There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate acute-dietary

risk to the general population, including infants and children, or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) 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: Tolerance level residues were assumed for all commodities associated with PP 1F6313 with the exception of a few crops where levels higher than the tolerance were used. The latter were due to the lowering of some tolerances to harmonize with Canadian MRL's subsequent to the dietary risk assessment. Pome fruit and hops were also included from PP 2F6434 using the likely tolerance levels. One hundred percent crop treated was assumed for all commodities. Processing factors were either empirical or the default values in DEEM.