

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AZOXYSTROBIN 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 (general population including infants and children)	NOAEL=<200 mg/kg/day UF=300 Acute RfD=0.67 mg/kg/day	FQPA SF = 1X aPAD = Acute RfD + FQPA SF = 0.67 mg/kg/day	Acute neurotoxicity study in rats LOAEL = 200 mg/kg/day based on diarrhea and 2 hours post dose at all dose levels up to and including 20 mg/kg/day (the LOAEL)
Chronic dietary (all populations)	NOAEL = 18 mg/kg/day UF=100 Chronic RfD = 0.18 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD + FQPA SF = 0.18 mg/kg/day	Combined chronic toxicity carcinogenicity feeding study in rats LOAEL = 34/117 mg/kg/day in males/females based on reduced body weights in both sexes and bile duct lesions in males.
Short-term (1–7 days) incidental oral (residential)	NOAEL = 25 mg/kg/day UF = 100	FQPA SF = 1X	Prenatal developmental oral toxicity study in rats LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.
Intermediate-term (1 week to several months) incidental oral (residential)	NOAEL = 20 mg/kg/day UF = 100	FQPA SF = 1X	90–Day feeding study in rats LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition.
Short- intermediate-, and long-term dermal (residential)	None	None	21–Day repeated dose dermal study in rats. No dermal or systemic toxicity was seen at the limit does (1,000 mg/kg/day). This risk assessment is not required.
Short-term inhalation (1-7 days) (residential)	Oral Study NOAEL = 25 mg/kg/day (inhalation absorption rate - 100%)	LOC for MOE = 100 (residential)	Prenatal developmental oral toxicity study in rats. LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence and salivation.
Intermediate-term inhalation (1 week to several months) (residential)	Oral Study NOAEL = 20 mg/kg/day (inhalation absorption rate - 100%)	LOC for MOE = 100 (residential)	90–Day feeding study in rats LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition.
Long-term inhalation (>180 days) (residential)	None	None	This risk assessment is not applicable to the use of azoxystrobin
Cancer (oral, dermal, inhalation)	None	None	Azoxystrobin is classified as not likely to be carcinogenic in humans

2. *Metabolite toxicology.* There are no metabolites of concern based on a differential metabolism between plants and animals.

3. *Endocrine disruption.* There is no evidence that azoxystrobin is an endocrine disrupter.

C. Aggregate Exposure

1. *Dietary exposure.* Tolerance values have been established (40 CFR 180.507(a)) for the combined residues of both azoxystrobin and its Z isomer, in or on a variety of raw agricultural commodities including meat, milk and eggs. These established tolerances range from 0.02 ppm on tree nuts to 55 ppm on soybean hay.

i. *Food.* Tier I acute and chronic dietary exposure evaluations were made using the Dietary Exposure Evaluation

Model (DEEM®), version 7.76 from Exponent. All processing factors used DEEM® defaults values. All consumption data for these assessments were taken from the USDA's Continuing Survey of Food Intake by individuals (CSFII) with the 1994–1996 consumption data base and the Supplemental CSFII children's survey (1998) consumption data base. These dietary exposure assessments included all registered uses and proposed uses on asparagus (0.02 ppm), brassica, head and stem subgroup 5A (3 ppm), herb subgroup 19A (250 ppm) and artichoke globe (4 ppm).

ii. *Drinking water.* There is no established maximum concentration level (MCL) for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water

have been established. The concentration of azoxystrobin in surface water is based on generic estimated environmental concentration (GENEEC) modeling and in ground water based on screening concentration in ground water (SCI-GROW) modeling.

2. *Non-dietary exposure.* Azoxystrobin is registered for residential use on ornamentals and turf. The Agency evaluated the existing toxicological data base for azoxystrobin and assessed both the appropriate toxicological endpoints and the dose levels of concern. Dermal absorption data indicate that absorption is less than or equal to 4%.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish,