

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUMIOXAZIN

Endpoint	Dose (mg/kg/day)	HIARC/FQPA determination	Conclusion
Acute Dietary	NOAEL = 3.0 UF = 100	Cardiac effects (interventricular septal defects) were seen in the oral developmental and supplemental pre-natal studies in rats.	This risk assessment is required for the population subgroup Females 13–50. Acute RfD=0.03 mg/kg/day
Chronic Dietary	NOAEL = 2 UF = 100	Kidney effects were seen in males and anemia was seen in females in the 2-year toxicity study in rats.	This risk assessment is required. Chronic RfD =0.02 mg/kg/day.
FQPA Safety Factor	NA	Safety factor was retained because (1) there was evidence of increased susceptibility of fetuses exposed to flumioxazin by both the oral and dermal route in the prenatal developmental toxicity studies in rats, (2) there was evidence of increased susceptibility of young animals exposed to flumioxazin in the 2-generation reproduction toxicity in rats, and (3) there is concern for the severity of the effects in fetuses and young animals when compared to the maternal or parental animals.	10x Safety factor was retained aPAD=0.003 mg/kg/dy cPAD=0.002 mg/kg/dy
Carcinogenicity	NA	The HIARC determined that flumioxazin is “not likely” to be a human carcinogen (HIARC Memo, In Review).	A cancer risk assessment is not required.

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.568) for the residues of flumioxazin, in or on peanuts and soybean seed. Risk assessments were conducted by EPA to assess dietary exposures from flumioxazin 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 (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 acute exposure assessments: For this acute analysis the assumption was made that 100% of the crops with flumioxazin tolerances are treated with flumioxazin. In addition, the assumption was made that all commodities contain tolerance level residues when consumed, with the exception of those with default processing factors. Default processing factors were used for peanuts-butter (1.89x) and for soybeans-sprouted seeds (0.33x). As the exposure and risk estimates were low, no further refinements were made to this analysis.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as

reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For this chronic analysis the assumption was made that 100% of the crops with flumioxazin tolerances are treated with flumioxazin. In addition, the assumption was made that all commodities contain tolerance level residues when consumed, with the exception of those with default processing factors. Default processing factors were used for peanuts-butter (1.89x) and for soybeans-sprouted seeds (0.33x). As the exposure and risk estimates were low, no further refinements were made to this analysis.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flumioxazin 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 flumioxazin.

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 Screening Concentration in Ground Water Modeling System (SCI-GROW), which predicts pesticide concentrations in ground water. 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 percent of the reference dose or percent of the population adjusted dose (%RfD or %PAD). Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on