

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of

the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of famoxadone on vegetables, fruiting, group 8 (except tomato) at 4.0 ppm; tomato at 1.0 ppm; vegetables, cucurbit, group 9 at 0.30 ppm; lettuce, head at 10.0 ppm; potato at 0.02 ppm; grape at 2.50 ppm; grape, raisin at 4.0 ppm; fat of cattle, horses, goats, sheep at 0.02 ppm; liver of cattle, horses, goats, sheep

at 0.05 ppm and milk, fat (reflecting negligible residues in whole milk) at 0.060 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by famoxadone are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rats	NOAEL = Male (M): 3.3 milligrams/kilogram/day (mg/kg/day); Female (F): 4.2 mg/kg/day. LOAEL = M: 13.0 mg/kg/day based on mild hemolytic anemia and decreased glucose. F: 16.6 mg/kg/day based on decreased body weight gain, food consumption, and food efficiency; mild hemolytic anemia and decreased globulin.
870.3100	90-Day oral toxicity in mice	NOAEL = M: 62.4 mg/kg/day; F: 79.7 mg/kg/day. LOAEL = M: 534 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen and mild hepatotoxicity in the liver. F: 757 mg/kg/day based on mild hemolytic anemia with secondary responses in spleen and mild hepatotoxicity in the liver.
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL = M: 1.3 mg/kg/day; F: 1.4 mg/kg/day LOAEL = M: 10.0 mg/kg/day based on lens cataracts in eyes. At 23.8/21.2 mg/kg/day, also myotonic twitches (starting on day 21); decreased body weight, body weight gain, food consumption, and food efficiency; slight anemia and hyperkalemia. F: 1.4 mg/kg/day based on lens cataracts in eyes. At 10.1 mg/kg/day, no additional effects. At 23.3/20.1 mg/kg/day, same effects as for males at 23.8/21.2 mg/kg/day.
870.3200	28-Day dermal toxicity in rats	NOAEL = M: 250 mg/kg/day; F: 1,000 mg/kg/day LOAEL = M: 500 mg/kg/day based on increased alkaline phosphatase, alanine aminotransferase and sorbitol dehydrogenase; and mild hepatotoxicity in the liver. F: none (>1,000 mg/kg/day). No dermal irritation in M or F.
870.3700	Prenatal developmental in rats	Maternal NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day based on transient decreased body weight gain and food consumption. Developmental NOAEL = 1,000 mg/kg/day LOAEL = none (>1,000 mg/kg/day)
870.3700	Prenatal developmental in nonrodents (rabbits)	Maternal NOAEL = 350 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions; decreased body weight, body weight gain, and food consumption; and abnormal stools. Developmental NOAEL = 350 mg/kg/day LOAEL = 1,000 mg/kg/day based on abortions and equivocal increases in postimplantation loss and mean resorptions per dose.