

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 etoxazole on cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; fruit, pome, group 11 at 0.20 ppm; apple, wet pomace at 0.50 ppm; strawberry at 0.50 ppm; tangerine at 0.10 ppm; liver of cattle, goat, horse, and sheep at 0.01 ppm; fat of cattle, goat, horse, and sheep at 0.02 ppm; and

milk, fat at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances 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 etoxazole 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 rodents (rat)	NOAEL = 61.8/69.0 milligrams/kilogram/day (mg/kg/day) Male/Female (M/F) LOAEL = 183.7/204.8 mg/kg/day (M/F), based upon increases in hepatic enzyme levels, increased liver weights and centrilobular hepatocellular swelling in both sexes and liver enlargement in females only
870.3100	90-Day oral toxicity rodents (rat)	NOAEL = not determined LOAEL = 300.4/336.6 mg/kg/day (M/F), based upon clinical signs, clinical chemistry, increased liver weights, and histopathology
870.3100	90-Day oral toxicity rodents (mouse)	NOAEL = 213.6/250.5 mg/kg/day (M/F) LOAEL = 878.4/994.5 mg/kg/day (M/F), based upon periportal hepatocellular necrosis, increased alkaline phosphatase levels, accompanied by increased relative liver weight, liver enlargement, and centrilobular hepatocellular swelling
870.3150	90-Day oral toxicity in non-rodents (dog)	NOAEL = 5.33/5.42 mg/kg/day (M/F) LOAEL = 53.7/55.9 mg/kg/day (M/F), based upon clinical signs (vomiting foamy fluid and mucous stool), clinical chemistry, increased liver weights, and centrilobular swelling in the liver and acinar cell atrophy in the prostate
870.3200	21/28-Day dermal toxicity (rabbit)	NOAEL = 1,000 mg/kg/day (M/F) LOAEL = not determined. No systemic effects noted
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 1,000 mg/kg/day LOAEL = not determined Developmental NOAEL = 1,000 mg/kg/day LOAEL = not determined
870.3700	Prenatal developmental toxicity in nonrodents (rabbit)	Maternal NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based upon liver enlargement and decreased body weight gains and food consumption Developmental NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based upon increased incidences of 27 presacral vertebrae and 27 presacral vertebrae with 13th ribs in the fetuses