

byproducts at 1.0 ppm; sugarcane at 0.01 ppm, and tomato at 0.01 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will 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 a tolerance for residues of trifloxysulfuron on almond at 0.02 ppm; almond, hulls at 0.01 ppm; fruit, citrus,

group 10 at 0.03 ppm; cotton, undelinted seed at 0.05 ppm; cotton gin byproducts at 1.0 ppm; sugarcane at 0.01 ppm; and tomato at 0.01 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 trifloxysulfuron 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 (rats)	NOAEL: 507/549 milligrams/kilogram/day (mg/kg/day) Male/Female (M/F) LOAEL: 1052/1128 mg/kg/day (M/F): M = decreased body weight, decreased body weight gain, equivocal increased testicular atrophy at end of recovery phase; F = decreased body weight, decreased body weight gain, equivocal slightly increased histopathology in liver (single cell necrosis, focal necrosis, inflammation, hepatocellular hypertrophy).
870.3100	90-Day oral toxicity rodents (mice)	NOAEL: 1,023/1,507 mg/kg/day (M/F) LOAEL: >1,023/>1,507 mg/kg/day (M/F): M = not attained; F = not attained.
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL: 19.8/19.6 mg/kg/day (M/F) LOAEL: 164.2/167.3 mg/kg/day (M/F): M = decreased body weight gain (20%), slight hematological effects, clinical chemistry changes suggesting hepatotoxicity, decreased thymus weight, thymic atrophy, increased glycogen in liver, hemorrhage in mesenteric lymph nodes; F = decreased body weight gain (44%), anemia with extramedullary hematopoiesis in liver/spleen and myeloid hyperplasia in bone marrow, clinical chemistry changes suggesting hepatotoxicity, decrease thymus weight, thymic atrophy and hyaline tubular change in kidney.
870.3200	21/28-Day dermal toxicity (rats)	NOAEL: 1,000/100 mg/kg/day (M/F) LOAEL: >1,000/1,000 mg/kg/day (M/F): M = not attained; F = decreased body weight gain. No dermal irritation M/F.
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL: 300 mg/kg/day Maternal LOAEL: 1,000 mg/kg/day based on decreased food consumption during treatment, decreased body weight gain during post-treatment. Developmental NOAEL: 300 mg/kg/day Developmental LOAEL: 1,000 mg/kg/day based on slight decrease in fetal weight, increased skeletal anomalies, increased poor/absent skeletal ossification.
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL: 100 mg/kg/day Maternal LOAEL: 250 mg/kg/day based on increased mortality, increased vaginal/anal bleeding. Developmental NOAEL: 50 mg/kg/day Developmental LOAEL: 100 mg/kg/day based on abnormally shaped heart (one fetus at 100 mg/kg/day and 3 fetuses from 2 litters at 250 mg/kg/day).