

assessment since these residues are significantly lower than those in feed items from the crops which are treated directly with clothianidin and/or thiamethoxam. Tolerances are established on animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 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 tolerances for residues of clothianidin on canola, seed at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk

removed at 0.01 ppm; corn, field, forage at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, sweet, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; and milk at 0.01 ppm, animal feed, nongrass at 0.02 ppm; grain, cereal, forage, fodder and straw at 0.02 ppm; grass, forage, fodder and hay at 0.02 ppm; soybean, forage at 0.02 ppm; and soybean, hay at 0.02 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 clothianidin 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: 27.9/34.0 milligrams/kilogram/day (mg/kg/day) (male/female) LOAEL: 202.0/254.2 mg/kg/day (male/female: decreased body weight (bwt) and bwt gain)
870.3150	90-Day oral toxicity in nonrodents (dogs)	NOAEL: 19.3/42.1 mg/kg/day (male/female) LOAEL: 40.9/61.8 mg/kg/day (thinness, decreased bwt, bwt gain and anemia (one male); decreased white blood cells, albumin, and total protein (female))
870.3200	21/28-Day dermal toxicity (rats)	NOAEL: 1,000 mg/kg/day (highest dose tested) LOAEL: > 1,000 mg/kg/day
870.3700	Prenatal developmental in rodents (rats)	Maternal NOAEL: 10 mg/kg/day Maternal LOAEL: 40 mg/kg/day (decreased bwt gain and food consumption) Developmental NOAEL: 125 mg/kg/day Developmental LOAEL: cannot be established
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL: 25 mg/kg/day Maternal LOAEL: 75 mg/kg/day (increased incidences of clinical signs (scant feces and orange urine), mortalities, decreased food consumption, early delivery, abortion, and decreased bwt gain) Developmental NOAEL: 25 mg/kg/day Developmental LOAEL: 75 mg/kg/day (premature deliveries, decreased gravid uterine weights, an increased litter incidence of a missing lobe of the lung and decreased litter average for ossified sternal centra per fetus)