

leafy, group 5, except broccoli at 10.0 ppm (2E6510), broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10.0 ppm, and kidney of cattle, goat, hog, horse, and sheep at 0.2 ppm, and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheep at 0.05 ppm (2E6510).

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 cyromazine on leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 ppm, garlic, bulb; garlic, great-headed, bulb; onion, dry bulb; rakkyo, bulb; and

shallot, bulb at 0.2 ppm, vegetable, brassica, leafy, group 5, except broccoli at 10.0 ppm, broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10.0 ppm, and kidney of cattle, goat, hog, horse, and sheep at 0.2 ppm, and meat byproducts, except kidney, of cattle, goat, hog, horse, and sheep at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 cyromazine 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	Subchronic oral-Dog	The systemic toxicity LOAEL is 1,000 ppm (25 mg/kg/day) based on alteration in liver weight in males. The systemic toxicity NOAEL is 300 ppm (7.5 mg/kg/day).
870.3100	Subchronic oral-Rat	The systemic toxicity LOAEL is 300 ppm (30 mg/kg/day), based on alteration in the liver weight changes in males. The systemic toxicity NOAEL is 30 ppm (3 mg/kg/day).
870.3200	21-day dermal toxicity-Rabbit	No treatment related systemic toxicity was noted. The systemic toxicity NOAEL > 2,000 mg/kg/day. The systemic toxicity LOAEL > 2,000 mg/kg/day. No dermal irritation was noted. The dermal toxicity NOAEL > 2,000 mg/kg/day. The dermal toxicity LOAEL > 2,000 mg/kg/day.
870.3200	21-day dermal toxicity-Rabbit	No treatment related systemic toxicity was noted. The systemic toxicity NOAEL > 2,010 mg/kg/day. The systemic toxicity LOAEL > 2,010 mg/kg/day. No dermal irritation was noted. The dermal toxicity NOAEL > 2,010 mg/kg/day. The dermal toxicity LOAEL > 2,010 mg/kg/day.
870.4100	Chronic oral (6-months)-Dog	The systemic toxicity LOAEL is 3,000 ppm (75 mg/kg/day) based on alteration in hematological parameters (hemoglobin, and hematocrit). The systemic toxicity NOAEL is 300 ppm (7.5 mg/kg/day).
870.4300	Combine Chronic/Carcinogenicity-Rat	The systemic toxicity LOAEL is 300 ppm (15 mg/kg/day) based on decreased body weight. The systemic toxicity NOAEL is 30 ppm. (1.5 mg/kg/day). There is no evidence of carcinogenicity.
870.4200	Carcinogenicity-Mouse	The systemic toxicity LOAEL is 1,000 ppm (150 mg/kg/day) based on decreased body weight. The systemic toxicity NOAEL is 50 ppm. (7.5 mg/kg/day). There is no evidence of carcinogenicity.